Exhibit D

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1
                     IN THE SUPERIOR COURT
                  OF NEW JERSEY LAW DIVISION
 2
                        BERGEN COUNTY
 3
    KATHRYN E. CORBET and ERIC
    R. CORBET,
 4
                  Plaintiffs,
                               ) MASTER DOCKET NO:
 5
                               ) BER-L-11575-14
    VS.
 6
    ETHICON, INC., ETHICON ) CIVIL ACTION: In re
 7
    WOMEN'S HEALTH AND
                              ) Pelvic Mesh/Gynecare
    UROLOGY, a Division of ) Litigation, Case No. 291
    Ethicon, Inc., GYNECARE,
 8
                              ) CT
    JOHNSON & JOHNSON, AND
 9
    JOHN DOES 1-20,
10
                  Defendants.
    11
12
               ORAL AND VIDEOTAPED DEPOSITION OF
13
                     WENXIN ZHENG, M.D.
14
                     NOVEMBER 18, 2015
15
    16
         ORAL DEPOSITION OF WENXIN ZHENG, M.D., produced as a
17
    witness at the instance of the Plaintiffs, and duly
18
    sworn, was taken in the above-styled and numbered cause
19
    on November 18, 2015, from 9:16 a.m. to 5:28 p.m.,
20
    before Lisa C. Hundt, CSR, RPR, CLR in and for the State
21
    of Texas, reported by machine shorthand, at the law
22
    offices of Thompson & Knight, located at 1722 Routh
23
    Street, Suite 1500, Dallas, Texas, in accordance with
24
    the New Jersey Rules of Civil Procedure and the
25
    provisions stated on the record or attached hereto.
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	2	FOR THE PLAINTIFFS:		NO. DESCRIPTION PAGE
	3	Daniel J. Thornburgh, Esquire And		Ex. 1 Notice of Video Deposition
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	5	AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC 17 East Main Street	5	D11vc)
		Suite 200		Ex. 3 Expert Report of Wenxin Zheng, M.D. Dated
	6	Pensacola, Florida 32502 850.202.1010	6	08/07/1411
	7	850.916.7449 Fax)	7	Ex. 4 Expert Report of Wenxin Zheng, M.D. (Brought by Witness)
	8	dthornburgh@awkolaw.com	8	(Drought by Withess) 12
	9	FOR THE DEFENDANTS:	9	Ex. 5 Expert Report of Dr. Iakovlev 12
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	18	615.651.6701 (Fax) Andy.snowden@butlersnow.com	19	
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- 1 A. Good morning.
- Q. How are you?
- 3 A. Okay.
- 4 Q. Good. Can you please state your name -- full
- 5 name for the record?
- 6 A. Wenxin Zheng.
- ⁷ Q. And is it pronounced Dr. Zheng?
- 8 A. That's fine.
- 9 Q. Okay. I'll do my best. If I butcher your
- 10 name during the deposition, I apologize.
- 11 A. That's okay. No problem.
- Q. Doctor, you've been deposed previously?
- ¹³ A. Correct.
- Q. Okay. How many times have you given a
- 15 deposition?
- A. I think three times.
- Q. Three times in the mesh litigation or three
- 18 times total?
- A. Three times for the mesh litigation.
- Q. And was that for the Lewis case -- the -- and
- 21 the Husky -- sorry, the Lewis case?
- A. Lewis case, Husky, and Edwards.
- O. Edwards.
- And did you have an opportunity to look at
- 25 the deposition notice?

- 1 A. Yes.
- 2 Q. Okay. I'll mark as Exhibit Number 1 the
- 3 deposition notice.
- 4 (Exhibit Number 1 was marked.)
- 5 Q. And when did you review the deposition notice?
- 6 A. Last week.
- 7 Q. Okay. And did you take some steps to gather
- 8 records that were responsive to the request for
- 9 production of documents attached to the deposition
- 10 notice?
- 11 A. Yes.
- MR. VOUDOURIS: Dan, if I can help you
- 13 out. His complete file, including his billing and
- 14 photographs, I understand, and literature is on this
- 15 jump drive.
- Q. (BY MR. THORNBURGH) We will mark as Exhibit
- 17 Number 2 to the deposition notice what counsel for
- 18 Ethicon, Johnson & Johnson, have provided to me, which
- 19 is purported to be your file in this case.
- 20 A. Yes.
- 21 (Exhibit Number 2 was marked.)
- Q. And what steps did you take to gather the
- 23 records responsive to the deposition notice?
- A. It's mainly from my computer, my desktop.
- Q. Okay. And what is your understanding of the

- Page 8
- 1 documents contained within Exhibit Number 2?
- 2 A. Can you rephrase your question?
- Q. Yeah. And -- and I apologize. If at any time
- 4 during the deposition, you don't understand my question,
- 5 just let me know, ask me to rephrase it --
- A. Sure.
- Q. -- or re-ask it, and I'll do my best --
- 8 A. Okay.
- 9 Q. -- to ask you a better question.
- 10 A. No problem.
- Q. But my question to you was: What document --
- 12 what is your understanding of the documents that are
- -3 contained on Exhibit 2?
- 4 A. My understanding is just whatever I have read,
- 5 whatever I produced for my report, maybe part of the
- 16 document you -- related to this case.
- Q. And I think counsel representing you here
- 8 today indicated that your billing records are contained
- 19 within Exhibit Number 2. Is that correct?
- 20 A. Correct.
- Q. Okay. And then your case file, what would
- 22 your case file include?
- A. What do you mean "case file"?
 - Q. The -- what -- what types of records did you
- 25 maintain in your case -- in your file for this case?
 - Page 9
 - A. Okay. Whatever the medical record for -- for
- ² the patient Corbet, I received, I will maintain, I will
- 3 keep in my desk -- in my desktop. And also, whatever
- 4 the draft I made for my report, I will maintain. And
- 5 also, the slides I reviewed, the pictures I took and
- 6 that, generally, also will be maintained in my file.
 - Q. Okay.
- 8 A. And, also, literatures I reviewed relevant to
- 9 this case also be main -- be maintained.
- Q. Okay. And so for the literature that you
- 11 reviewed relevant to this case, would that include --
- does Exhibit Number 2 have the documents -- all of the
- 13 literature that you reviewed that are -- that's
- 14 identified in your reliance list on your report?
- A. It's not necessarily in -- everything
- 16 inclusive, but I think more relevant articles I saved.
- Q. And you had indicated there were some photo
- 18 micrographs?
- 19 A. Yeah.
- Q. Okay. And are there photo micrographs
- 21 contained within Exhibit Number 2 that are in addition
- 22 to the photo micrographs that are contained within your
- 23 expert report?
- A. In a few of them, I think it's because when I
- generate my expert report, I have to use some of these

Case 2:12-md-02327 Document 2834-4 Filed 09/19/16 Page 5 of 73 PageID #: 98282 Wenxin Zheng, M.D. Page 10 Page 12 1 pictures rather than the whole pictures. But it's 1 MR. THORNBURGH: Pardon me? 2 still, all the pictures I took is maintained and it's in MR. VOUDOURIS: Exhibit 3? 3 the file. 3 MR. THORNBURGH: Exhibit 3, yeah. Q. Okay. Do you -- do you recall approximately Q. (BY MR. THORNBURGH) You have -- it appears 5 how many micro -- or photo micrographs are contained that you have some additional documents in front of you. 6 within Exhibit Number 2? 6 What do you have in front of you that you brought with 7 you today? A. Probably there's about 20, 25 pictures total. A. It's my expert report, the same thing as Q. And defense counsel had indicated also and I yours. And then Dr. Iakovlev's report. 9 think you confirmed that your invoice for the work that 10 you've performed in the Corbet case -- or invoices, Q. Okay. We'll go ahead and mark as Exhibit 11 perhaps -- are also contained within Exhibit Number 2? 11 Number 4 the expert -- your export report that you 12 A. Yes. I only billed once for that. 12 brought with you today. 13 13 A. Okay. Q. Okay. So one invoice? 14 14 A. Yes. (Exhibit Number 4 was marked.) 15 Q. Okay. And do you recall -- because I don't 15 A. Mine's a single page. Yours is double page, 16 have a --16 so... 17 17 A. How many hours? Q. Okay. And are there any -- did you make any changes or anything on Exhibit Number 4 different than 18 Q. Yeah. Do you recall how many hours you billed 18 19 on the invoice? Exhibit Number 3? 20 20 A. I didn't change at all. A. I think it's about 49 hours. That was from Q. And we'll mark as Exhibit Number 5 the report 21 21 last year. 22 22 you brought with you today regarding Dr. Iakovlev. Q. And is that at \$600 an hour? 23 A. Correct. 23 A. Yeah. Q. And so all of the work that you've performed 24 (Exhibit Number 5 was marked.) 25 25 last year, the 49 hours, would that represent the time Q. Did you bring any other documents with you Page 13 Page 11 1 that you spent preparing for -- preparing your expert 1 today other than the documents contained on Exhibit 2 report? 2 Number 2, the -- which is the thumb drive, or Exhibit A. Correct. Reading medical records, literatures 3 Number 3 and 4? 4 and prepare reports and reading slides, taking pictures, A. No. 5 to prepare for presentations. Q. Now, I know that you billed, you said, Q. Okay. How much time was spent reading the 6 49 hours last year in preparation for your expert 7 medical literature? report. How much time have you -- strike that. A. Maybe, I think, probably 50 percent of the 8 8 Regarding the 49 hours, do you know what 9 time. I can't be exact. the invoice date is? 10 Q. And what was the other 50 percent of your time 10 A. Last year sometime. I don't remember exactly. 11 devoted to? 11 Maybe --12 12 A. And then medical records, understanding the O. It will be identified on Exhibit Number 2, 13 whole situation. And then writing reports and pathology 13 right? analysis and photograph taking. A. Right. 15 Q. Have you done additional work in preparation (Exhibit Number 3 was marked.) 16 Q. I've marked as Exhibit Number 3 your expert for this case or this deposition that's not contained 17 report dated August 7th, 2014. within your invoices on Exhibit Number 2? 18 A. Yes. 18 A. Oh, yes. Because after a year, then, you 19 Q. Does this appear to be your full report in the 19 know, not really I can remember everything. 20 Corbet versus Ethicon case? 20 Q. Okay. 21 A. Yes. From the first page, it looks identical. A. So therefore, when I received a notice from 22 MR. THORNBURGH: Counsel. If you don't 22 Mr. Snowden saying this case is going to be on

23

24

MR. VOUDOURIS: I have my own copy.

23 need it...

25 It's 3?

24

deposition, and then I start to review again.

²⁵ reviewing and -- the case and preparing for this

Q. Okay. And how much time have you spent

1 deposition?

- A. Because I have additional medical records
- 3 coming that I have read. And then I do a new literature
- 4 search and additional findings. And then, also, have to
- 5 review my -- what I have written, because I may not
- 6 remember what I have done in the past. That's a year
- 7 ago.
- Q. Okay. So let me make sure I under -- I'm
- 9 sorry. Were you done?
- 10 A. Yeah.
- Q. Let me make sure I understand. So since last
- 12 year, you have -- and after the -- the date of your --
- 13 your invoice, you have reviewed additional medical
- 14 records. How much time have you spent reviewing
- 15 additional medical records?
- 16 A. Oh, I don't remember exactly, because this is
- 17 through e-mails, you know, from Butler's law office
- 18 sending -- e-mail these medical records, and I have to
- 19 download and read, probably, several hours. I have no
- 20 idea exactly how -- how many hours I have spent for
- 21 that.
- Q. Okay. You also indicated that you did a new
- 23 literature search and additional findings. What do
- 24 you -- how much -- well, strike that.
- You also indicated that did you a new

- A. I --
- 2 MR. VOUDOURIS: Objection; compound.

Page 16

Page 17

- 3 Go ahead.
- 4 THE WITNESS: Okay.
- 5 A. Okay. I think based on my impression, Hill's
- 6 article basically study the explant vaginal mesh
- 7 dividing into three groups. One group was, like, a
- 8 voiding dysfunction, then the other group is -- was pain
- 9 then /erosion and then the third group, combination of
- 10 these two. Then compared the amount of information they
- 11 found from histological findings.
- Q. (BY MR. THORNBURGH) And do you recall what
- 13 their conclusions were regarding voiding dysfunction?
- 14 A. Right. The conclusion is a little bit
- 15 surprise to me, also -- probably also, it's reasonable.
- 16 Because they found in the voiding dysfunction group,
- 17 these patients has highest amount of inflammation
- 18 compared to those patient complain with pain or even
- 19 erosion.
- 20 Q. And why was that significant or surprising to
- 21 you?
- A. Because, typically, if it's -- there is
- 23 erosion or exposure -- what's called mesh exposure to
- 24 outside surface -- then you should have more
- 25 inflammation.

- 1 literature search. How much time did you devote to
- ² doing additional literature searches?
- 3 A. Several hours. I think mainly I want to see
- 4 if there's any recent advances in the field to see, you
- 5 know, whether there's any new publications related to
- 6 this topic.
- 7 Q. Did you identify any additional new literature
- 8 that you felt was relevant to your opinions?
- 9 A. Yeah. I have the two most relevant
- 10 publications, I think. One is Hill's article. The
- 11 other is Dr. Smith's article regarding histological
- 12 finding from those explanted mesh specimens.
- Q. Okay. So Hill's article?
- 14 A. Right.
- Q. And I think you said Smith?
- 16 A. Smith.
- Q. Is that the same article?
- 18 A. Different.
- Q. Different articles?
- Did you include those two articles on --
- 21 within Exhibit Number 2?
- A. I believe it's there in the -- Exhibit
- 23 Number 2, yeah.
- Q. Okay. And what significance did the Hill and
- 25 Smith articles have in this case?

- Q. Okay. So was there an association made by
- 2 these authors or some of these authors that mesh
- 3 exposure was associated, number one, with an increased
- 4 inflammatory response, and, number two, with an
- 5 increased risk of voiding dysfunction?
- 6 MR. VOUDOURIS: Objection.
- Go ahead.
- 8 A. I don't think they -- they concluding that
- 9 way.
- 10 Q. (BY MR. THORNBURGH) What was their
- 11 conclusion? Did they correlate the two?
- 12 MR. VOUDOURIS: Objection.
- 13 A. I think they correlate mainly to see if the
- 14 inflammation may contribute one of these critical
- 15 findings, but their finding is they're more associated
- 16 with the voiding dysfunction group.
- Q. (BY MR. THORNBURGH) So increased inflammation
- 18 in women who have had mesh implants had an increased
- 19 risk of voiding dysfunction as a result of the
- 20 inflammation?
- 21 MR. VOUDOURIS: Objection.
- A. No. I -- I don't think that you can conclude
- 23 in that way. That's not in my understanding.
- Q. (BY MR. THORNBURGH) I think your answer was
- 25 they correlate mainly to see if the inflammation may

Page 18 Page 20 1 contribute to one of these critical findings, but their 1 erosion have less inflammation? 2 finding is they're more associated with the voiding A. Correct. That's their conclusion. Q. And then final -- you said the last subissue 3 group. What do you mean by that? A. It's -- that's -- that's the descriptive in the article was a combination of voiding dysfunction, 5 finding, all right? It's basically association. Does pain, and erosion. What do you mean by that? 6 not necessarily meaning one is the cause, the other is MR. VOUDOURIS: Objection. 6 the results. Go ahead. A. They combine these two groups and compare to Q. But in any event, they found that for women 9 implanted with mesh devices who had an -- had an see what happens. 10 Q. (BY MR. THORNBURGH) And what were their 10 increase in inflammatory response, there was an association -- or an increased association of voiding 11 conclusions when they combine the two groups? 12 A. They basically -- if they combine these two 12 dysfunction? 13 MR. VOUDOURIS: Object to form. groups, shows no difference between mesh exposure versus 14 Q. (BY MR. THORNBURGH) Is that -- is that fair pain and also in combination with voiding dysfunction. 15 and accurate? Q. And what was significant to you in your mind 16 A. I think my understanding is more inflammation 16 in -- for the Corbet case regarding the Hill article? 17 17 is associated with patients with voiding dysfunction. A. And I think overall, basically, inflammation 18 That's it. does not play a bigger role for mesh implants. I think 19 that's the overall message when I read this article. Q. And those patients had mesh implantation? 20 20 Q. What about voiding dysfunction? 21 21 Q. And you also indicated that there was -- that A. Voiding dysfunction, they found a little more 22 they looked at -- strike that. inflammation, mainly -- probably related to urinary 23 You also indicated that one of the things tract infection issues. Because when any patient has a that they studied -- I'm sorry. Strike that. voiding dysfunction, then has increase the chance to get 25 The voiding dysfunction, is that the Hill bacteria infection, therefore, more inflammation can be Page 19 Page 21 1 article or the Smith article? 1 found. A. That's in the Hill's article. Q. And what was significant in your mind Q. Okay. And the pain and erosion, is that the regarding their findings of pain and erosion? 4 Hill article or the Smith article? A. Pain --A. Also Hill's article. 5 MR. VOUDOURIS: Objection. Q. Okay. And --Go ahead. A. Those three groups I just mentioned that. A. Pain and erosion overall is a lower incidence 8 among all these -- the patients received mesh implants, Q. And what did the authors in the Hill article 9 conclude regarding women implanted with mesh devices and TVT or TVTO; overall is lower incidence. 10 the complications of pain and erosion? Q. (BY MR. THORNBURGH) What was the incidence 11 MR. VOUDOURIS: Objection. rate described in the Hill article concerning women 12 Go ahead. 12 implanted with mesh devices and pain and erosion? 13 A. I don't think they -- they try to concluding 13 A. And I think they -- based on the subjects they 14 that way. They just try to see whether these groups of studied -- I don't remember exactly how many -- you 15 these patients to have more inflammation maybe know, each group has how many patients there -- but associated with one or the other. That's the basic these patients does not also represent overall 17 population of the patient who received TVT or TVTO study. implants. 18 Q. (BY MR. THORNBURGH) And did they find that 18 19 women implanted with mesh devices who had an increase in Q. That's -- that's your opinion, right? 20 inflammation also had pain and erosion? 20 A. That's my understanding. 21 MR. VOUDOURIS: Objection. 21 Q. That wasn't the opinion of the authors of the 22 22 Hill article, correct? A. No. They have actually less. A. That's -- that's my understanding after Q. (BY MR. THORNBURGH) So it's your -- it's 23 24 your -- your testimony that the authors who published 24 reading this, yes.

25

25 the Hill article concluded that women who have pain and

Q. Is that your opinion, or was that the opinion

- 1 of the authors in the Hill article?
- 2 A. That's what I said. After reading this
- 3 article, my impression isn't that way. Okay. But if
- 4 you want to study this one, it's better probably to
- 5 read -- take this article again.
- 6 Q. Yeah, we'll -- we'll -- maybe what we'll do on
- 7 a break is we'll -- we'll print out those articles.
- 8 A. Right.
- 9 Q. Okay. We'll talk about --
- 10 A. And then we can study paragraph by paragraph.
- Q. Do you recall how many explants were analyzed
- 12 by the researchers in the Hill article?
- A. It's about over a hundred, yeah.
- Q. And do you recall which -- which devices were
- 15 analyzed?
- A. What do you mean "which devices"?
- Q. What -- was it sling -- mesh sling devices,
- 18 mesh devices used for repair of pelvic organ prolapse,
- 19 or a combination of the two?
- 20 A. I didn't pay that attention. Probably
- 21 majority of them, they're sling -- a sling device.
- Q. And regarding the Smith article, what -- what
- 23 was that article about?
- A. I think Smith article is interesting because
- 25 they noticed the -- pathology department, when they

- 1 different places.
 - Q. (BY MR. THORNBURGH) Okay. And you also

Page 24

Page 25

- 3 indicated that their finding was that 50 percent had no
- 4 microscopic examination?
- 5 A. Right. Based on the Smith article, they
- 6 mentioned that.
- Q. Does that mean that there were 50 percent of
- 8 mesh specimens that were not analyzed microscopically?
- A. They analyzed grossly and recorded grossly and
- 0 do not submit routinely for microscopic examination.
- 11 That's the classical way for pathology department to
- handle these so-called foreign body material.
- Q. And so was it the -- did the Smith authors --
- 14 the authors of the Smith article, did they suggest that
- 15 new protocols needed to be in place so that more of
- 16 these mesh specimens that are sent to pathology
- 17 departments are actually looked at and analyzed
- 18 microscopically?
- 19 A. I think so, yes, they did.
- MR. MORRIS: Is it -- is it Smith or
- 21 Schmidt?
- THE WITNESS: Smith, S-M-I-T-H.
- MR. MORRIS: Okay, thanks.
- Q. (BY MR. THORNBURGH) And for -- for Hill, is
- 25 it H-I-L-L?

1

Page 23

- 1 receive all these explanted mesh specimens, they have
- 2 very heterogeneous way to handle the specimen. So
- 3 therefore, they try to study to see if there any better
- 4 way to handle these specimen, more uniformly. Because
- 5 more and more these days, any hospitals they start to
- 6 receive more explanted specimens.
 - And then they found, actually in the past,
- 8 50 -- almost 50 percent of them, they just do not have
- 9 any microscopic examination. I think that's -- that's
- 10 the -- the -- the same experience I have encountered in
- 11 the past.

- Q. So let me back up a little bit on this -- on
- 13 the Smith article. Again, we'll print that out if we --
- MR. THORNBURGH: Is there a printer here
- 15 that we can have someone print an article during a
- 16 break, these articles?
- MR. VOUDOURIS: Sure. I imagine it
- 18 wouldn't be a problem.
- 19 Q. (BY MR. THORNBURGH) Okay. But to go back
- 20 real quick on the Smith article, you said that hospitals
- 21 are receiving more and more mesh explanted specimens?
- MR. VOUDOURIS: Objection.
- A. Correct. Based on my understanding, yes,
- 24 compared to the years -- like five years ago, yeah.
- 25 These days, more specimens coming to the hospital in

- A. Correct.
- Q. And are you in agreement with the authors of
- 3 the Smith article that for mesh specimens that are
- 4 explanted from women, more microscopic analysis needs to
- 5 be conducted?
- 6 A. I think so. Particularly in these days
- 7 because many legal issues involved, I think it's
- 8 reasonable to have a standard way to handle these
- 9 specimens should include microscopic examination.
- Q. Did they recommend a pathology registry
- 11 program where specimens would be provided to a central
- 12 location or locations, analyzed microscopically and then
- 13 the pathological findings reported in the registry?
- 14 A. I don't remember they have this kind of
- 15 sentence, no.
- Q. Did they discuss the number of mesh specimen
- 17 explants at any particular hospital?
- A. I think also from the single institution, from
 - 9 their institution. I don't remember which one is that.
- 20 But it's recorded in the -- in the publication.
- Q. Okay. So they -- they were reporting on their single institution?
- A. I think -- my memory -- I didn't pay detail
- 24 attention to where these specimens came from. I think I
- 25 just answered the overall situation. That was my

Page 26 Page 28 1 report, basically within a year period. 1 impression. 2 Q. Did they indicate in their publication how Q. Okay. So you were -- when you said additional 3 many mesh explant specimens have been received by their 3 findings, you weren't talking about additional findings 4 institution? with respect to your review of the --5 A. I think it's -- it's better to review the A. Of the literature. I mean, additional --6 MR. VOUDOURIS: Hold on. Doctor --6 material method in the article. Sir, let me ask you, you are reading Q. (BY MR. THORNBURGH) Yeah. Let me try to whatever -- it's already recorded? finish the question. 9 MR. THORNBURGH: Yeah, off the --Because -- you weren't -- you were only 10 MR. VOUDOURIS: Off the record. talking about the literature, you weren't talking about 11 THE WITNESS: It's a simultaneous -additional findings with respect to either your review 12 THE REPORTER: Wait, wait. Off the record of updated medical records or your review or re-review 13 or -of the pathological specimens that you have related to 14 MR. VOUDOURIS: Off the record. Ms. Corbet? THE REPORTER: Let the videographer... 15 15 A. Let me, yeah, rephrase my answer. So 16 THE VIDEOGRAPHER: Off the record at basically, additional findings that's additional 17 9:46 a.m. literature findings. 18 (Off the record.) Q. Okay. 19 THE VIDEOGRAPHER: We're back on record at 19 A. It's not additional pathological findings from 20 9:47 a.m. 20 Corbet case. Q. (BY MR. THORNBURGH) Okay. So let's go back 21 21 Q. So the additional -- additional time that you 22 to the question I'd asked before we started talking 22 spent preparing for this deposition was also your review 23 about the Hill and the Smith articles. 23 of -- your re-review of the medical records and your 24 A. Okay. 24 report? 25 25 Q. And I'd asked you how much time you'd spent in A. Yes. I have to refresh my mind, because Page 27 Page 29 1 the case -- this case preparing for this deposition. 1 that's -- that was written a year ago and I don't expect ² And you had indicated that you had additional medical ² myself I can remember everything I have done. 3 records, and then you did a new literature search, and Q. Okay. Did you review any additional -- strike 4 you identified Hill and Smith. Are there any other new 4 that. ⁵ literatures -- or new -- strike that. Were you provided with any additional Were there any other new articles that you 6 internal Ethicon documents? ⁷ found to be relevant and significant to your opinions? A. Yes. Q. And did you -- the reason why I'm asking this 8 A. I think many of the articles I have read, but 9 I don't think will influence my opinions regarding the question is because I never received a supplemental --10 pathology part, so therefore, I did not pay a lot of 10 you haven't supplemented your expert report, right? 11 attention to this. 11 A. I don't have any supplement expert report. 12 12 Q. So you didn't -- you didn't rely on any Q. And you haven't supplemented your reliance 13 additional articles since your report that you thought 13 list, correct? Your -- the list of materials that were significant or relevant in -- in your opinion? you're relying on? 15 A. Correct. 15 A. No. 16 16 Q. Other than the Smith and the Hill articles? Q. All right. You haven't --17 17 A. Because these are two pathology-related A. No, I haven't. 18 articles, pathological findings. It's similar work what 18 Q. -- supplemented your reliance list or your 19 I'm doing. 19 expert report? Q. Okay. You -- after you had indicated that you 20 A. No.

23

24

23 findings"?

24

21 did a new literature search, you also said that -- and

22 additional findings. What did you mean by "additional

A. Additional articles, basically. You have --

you do have several other articles published after my

Q. The additional internal Ethicon documents that

Are you saying that you've reviewed

you claim to have reviewed since your report was --

strike that. Let me just make sure I understand.

25 additional internal documents since you -- since you

- 1 drafted and served and signed your expert report?
- 2 A. Yes.
- 3 Q. Okay. Are those additional internal Ethicon
- 4 documents contained within Exhibit Number 2, the thumb
- 5 drive?
- A. I think so. 6
- 7 MR. VOUDOURIS: They are.
- 8 Q. (BY MR. THORNBURGH) Do you recall which -- or
- 9 what internal Ethicon documents you have reviewed which
- 10 are contained within Exhibit Number 2?
- 11 A. I don't remember exactly what's the name of
- 12 these documents, but I think if you really want to be
- 13 sure what I -- what was included, you may just print a
- 14 list, then we can discuss would be better.
- 15 Q. Do you recall what relevance those new
- 16 additional Ethicon internal documents had with respect
- 17 to this case?
- A. I think there is one interesting internal 18
- 19 study by Mr. McLean -- or I'm not sure what last name.
- Q. Dr. Berkeley? 20
- A. McLean -- I have no -- not exactly. Start 21
- 22 with M, anyway. Okay. And -- yeah, if you can show me,
- 23 that would be better, if you have it.
- Q. Well, you know, what we'll do is, on a break,
- 25 we'll look at your Exhibit Number 2 --
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- 1 A. Right.
- Q. -- and we'll have any additional Ethicon
- 3 documents printed.
- A. If you would like to print out, that would be
- 5 better that way.
- 6 Q. Okay. Any other -- is it just one additional
- 7 internal Ethicon document?
- 8 A. Yeah. I think this one, because he did some
- experiments that -- that's interesting experiments.
- 10 Q. And what interesting experiments were
- 11 conducted?
- 12 A. So basically, the experiments was to try to
- 13 demonstrate if the TVT filaments after oxidization then
- 14 can generate these, like, bark-like material or can
- 15 retain the stainings as -- as suggested by Dr. Iakovlev.
- 16 And then the conclusion is -- the answer is no.
- 17 Q. Okay. So let me just make sure I understand.
- 18 So --
- 19 A. Right.
- Q. So you -- what you thought was an internal --
- 21 or what you -- what you represented as being an internal
- 22 Ethicon document is actually not an internal Ethicon
- 23 document but the expert report of Dr. Steven McLean?
- 24 A. Steven McLean, yes, correct.
- 25 Q. Okay.

- A. Is this the one you refer to or no? This
- 2 is --
- 3 Q. Well, I had asked -- my question to you was,
- what internal Ethicon documents have you reviewed?
- A. Oh. I -- I believe this looks like internal,
- because not, like, published already.
- Q. You understand that Dr. McLean is not
- identified or disclosed as an expert in the Corbet case?
- Do you know that?
- A. I -- I'm not aware of this. But anyway, this
- is the material I received and that I read. Because I
- don't have habit to correlate who represents who and
- what is what for those. And these -- these documents --
- when I review I feel is interesting, that's it.
 - Q. Okay. And so you're talking about the -- the
- opinions of Dr. McLean concerning his experiments of
- intentionally oxidizing TVT mesh specimens?
 - A. Yes.

18

21

- 19 Q. Okay. And do you recall how he attempted to
- intentionally oxidize those mesh specimens? 20
 - MR. VOUDOURIS: Objection.
- 22 Go ahead.
- 23 A. Not in detail. But I think if we can open the
- 24 document and read through and I think that will refresh
- 25 my mind a little bit.

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- Q. (BY MR. THORNBURGH) Okay. Do -- do you
- 2 recall him conducting in part of his experiment a test
- 3 to -- strike that.
- Do you recall that as part of his
- experiment he did use UV light?
- A. UV light as the -- as a demonstrative method
- for oxidization, that's true.
- Q. Okay. And -- and UV light is -- strike that.
- You'd agree with me that women that have
- mesh implanted in their bodies, their mesh isn't exposed
- to UV light, correct?
- A. That's different. That's true. However, the
- point is, because there is in no way to do a human --
- use a human body or use a woman to do experiments like
- 15 this at this moment, because ethically it's not
- 16 allowed --
- 17 Q. My -- my --
- 18 A. -- and also not practical.
- 19 Q. I'm sorry. But my question was, you
- understand that UV light does not mimic the degradation
- process that occurs in the human body when the mesh --
- the mesh specimens are exposed to enzymes, neutrophils,
- 23
- macrophages, and -- and things of that nature, correct? 24 MR. VOUDOURIS: Objection; form.
- 25
 - A. From that point of view, yes. However,

- 1 because the -- degradation -- the overall degradation
- 2 process claimed by Dr. Iakovlev is because of these
- 3 inflammatory cell that produce oxidative -- oxidative
- 4 stress. Therefore, these oxidative stress can be
- 5 mimicked by some other way to try to simulate similar
- 6 condition. That's the experiment.
- 7 Q. (BY MR. THORNBURGH) Right. But the ex vivo
- 8 experiment conducted by Dr. McLean, you would agree,
- 9 would -- used UV light to radiate the mesh specimens
- 10 which doesn't occur in the human body?
- 11 A. That's different thing, yes.
- Q. So you agree with me?
- A. I think from that point of view, yes, you have
- 14 a correct statement.
- Q. And the second experiment that he performed
- 16 was using chemicals where he exposed mesh -- a mesh --
- 17 or mesh specimens to certain oxidizing chemicals for a
- 18 period of about four and a half weeks?
- 19 MR. VOUDOURIS: Objection.
- 20 A. I don't remember exactly how long, what
- 21 exactly he did. I think if you really want to review
- 22 what is the process, I think it's better to read the
- 23 article rather than just based on my memory. Because
- 24 these days, in addition to prepare the -- the
- 25 deposition, I also have to work. I have many other

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 1 evidence of degradation. That's -- that's why I barely
- 2 pay attention to these electron microscopic kind of
- 3 very -- you magnify those things to a very high level to
- 4 see these cracks. You know, those -- for me, it's
- 4 See these cracks. Tou know, those -- for the, it's
- 5 really not relevant. That's the -- basically, that's my
- 6 understanding. Therefore, I don't -- do not pay
- 7 attention to those.
- 8 Q. (BY MR. THORNBURGH) So you don't consider the
- 9 medical or scientific publications that have been
- 10 published in peer-reviewed articles that looked at
- 11 explanted meshes after a period of time in -- in the --
- 12 in the body and used techniques such as scanning
- 13 electron microscopy and concluded that the mesh had
- 14 degraded in vivo?
- MR. VOUDOURIS: Objection; form,
- 16 foundation.
- Q. (BY MR. THORNBURGH) Let me ask -- let me --
- 18 let me ask a better question. You didn't consider any
- 19 of the scientific or medical peer-reviewed publications
- 20 where the scientists had concluded that the mesh had
- 21 degraded in vivo?
- 22 MR. VOUDOURIS: Objection; form,
- 23 foundation.
- A. Well, as I said, based on my own experience
- 25 and I do not see any evidence of degradation, that's

- 1 things. I'm not the full-time just work on this, okay,
- 2 so...
- Q. (BY MR. THORNBURGH) Did you consider any of
- 4 the publications concerning in vivo degradation which
- 5 found that in order to identify through scanning
- 6 electron microscopy or other techniques -- strike that.
- 7 Did you look at any -- or consider any of
- 8 the publications, medical or scientific publications,9 which indicate that in order to get breaking on the
- 10 (1 11 11 11 11 11 11 11
- 10 outer shell or cracking on the -- the surface layer of
- 11 implanted meshes, that they have to be implanted for a
- 12 period of about a year or more?
- MR. VOUDOURIS: Objection; form,
- 14 foundation.
- 15 A. I still don't understand what your question.
- 16 Q. (BY MR. THORNBURGH) Yes. So let me -- I -- I
- 17 think I asked a very poor question, so let me try again.
- Did you consider any scientific or medical
- 19 publications that concluded that in order for mesh to
- 20 crack on the surface, to identify cracks on the surface,
- 21 that mesh needs to be implanted for a period of longer
- 22 than one year?
- MR. VOUDOURIS: Same objection.
- A. I'm a pathologist, okay? I read slides and
- 25 the microscope. Was my experience, I did not see any

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 1 number one. Because from tissue response to -- adjacent
- 2 to the mesh, whether there is a so-called bark-like
- 3 material or no bark-like material, all the tissue
- 4 response, they look the same, similar, number one.
- 5 Number two is, there is no any clinical
- 6 significance regarding these so-called degrade -- the
- 7 bark-like material with or without shows any clinical
- 8 difference from those patients. So therefore, my
- 9 understanding is there is no meaning -- or no evidence
- 10 to say to -- to -- to lead me to look for evidence that
- 11 there is a truly degradation from those implants.
- MR. THORNBURGH: Okay. Move to strike
- 13 nonresponsive to my question.
- Q. (BY MR. THORNBURGH) My question was simply:
- 15 You testified that you didn't find the studies that
- 16 looked at explanted meshes using scanning electron
- 17 microscopy and concluded that the mesh had degraded to
- 18 be relevant to you --
- 19 A. Correct.
- Q. -- in this case, right?
- 21 A. Correct. Therefore, I did not pay attention
- 22 to these articles.
- Q. So you didn't consider them, right? It's a
- 24 simple question.
- MR. VOUDOURIS: Objection.

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A. I did not read these articles.

1 trying

Q. (BY MR. THORNBURGH) Okay.

3 A. Okay.

1

Q. Doctor, what is -- in the path -- in the

5 pathology field, do you understand what I mean by

6 chatter? Do you know what chatter is?

A. I don't know what is chatter. Can you

8 explain?

9 Q. Yeah. Have you -- when a -- when a microtome

10 is used --

11 A. Uh-huh.

Q. -- and cuts through, you know, has a

13 cross-section, the mesh tissue and specimen -- strike

14 that.

12

When a microtome is used to create

16 slides --

17 A. To make sections.

Q. -- can a microtome sometimes scratch the

19 surface of the -- for example, a polymer -- and cause

what is known in the pathology field to be chatter or an

21 artifact?

MR. VOUDOURIS: Objection.

A. Yeah. That's so-called a cutting artifact, a

24 section artifact. That's very common in the pathology

25 lab.

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1 trying to analyze, that is an indication that you need

2 to -- need to change the blade of the microtome, right?

3 MR. VOUDOURIS: Objection. Hold on a

4 second, Dan. We talked about before and there's

5 agreement that this deposition is case specific to

6 Corbet. He just answered you, and he told you that he

7 didn't find any artifact when he looked at the Corbet

8 slide. So I think you're going past the agreement about

9 fact specific Corbet questions.

.0 MR. THORNBURGH: Well, I'm not -- number

11 one, I'm not trying to do that and that's not my

12 intention. He had indicated that an additional thing

13 that he has reviewed since his expert report was served

14 was the McLean report. And so I'm asking him questions

5 that are relevant to the McLean report.

MR. VOUDOURIS: Well, they're not relevant

17 to Corbet, but...

MR. THORNBURGH: If he's relying on them

19 in this case -- if he's not relying on it, then that's

20 fine

MR. VOUDOURIS: You didn't ask him if he

22 was relying on that -- that part of McLean for his

23 opinions in this case.

Q. (BY MR. THORNBURGH) Are you relying on the

Page 41

25 McLean -- Dr. McLean's report?

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Q. (BY MR. THORNBURGH) Have you heard of it

2 referred to as chatter before?

3 A. No.

Q. In any event, it's when the microtome causes

5 scratching on -- on the specimen that you're analyzing

6 under the microscope?

7 A. Right.

8 Q. And that's just an artifact caused from the

9 blade, right?

10 A. Right. That's related to the blade. That's

11 why there is a rule after a certain usage, the blade

12 should be changed.

Q. And if you are seeing this artifact on

14 specimens that you're analyzing, does that indicate to

15 you that the blade should be changed?

MR. VOUDOURIS: Objection.

A. It is not obvious in the routine microscope

18 examination from this Corbet case, okay? I do not see

19 apparent sectioning artifact to cause like a

20 fragmentation or scratch linings, those things, I don't

21 see that

13

16

Q. (BY MR. THORNBURGH) No, I'm not -- I'm not

23 asking you in this case. I'm just saying, generally, as

24 a pathologist, if you are getting this artifact of the

25 microtome blade scratching the specimen that you're

A. I'm not fully rely on Dr. McLean's report, but

² I -- as I mentioned, when I read through his report,

3 looks -- sounds interesting. And because there is

4 particle issue there, staining issue, that's relevant to

5 what Dr. Iakovlev claim, so that's -- that was the

6 reason.

Q. Have you reviewed any other -- or strike that.

8 So to go back to my original question,

9 have you reviewed any additional Ethicon internal

10 documents, and your response was you looked at the

11 McLean expert report. So let me try to clarify. Have

12 you looked at any additional Ethicon internal documents

since you issued your expert report?

A. I don't remember many other -- there is one

15 old report I briefly scanned through. That was back to

16 1983, something like this kind of report. That was a

17 long time ago. But the pictures, the printout -- the

18 pictures is very poor quality. They not look very good,

19 so, therefore, I did not pay much attention to that.

20 But I did receive this.

Q. So you looked at some internal document dated

22 from 19 -- from the 1980s that you looked at but you

23 disregarded because the pictures were not of good

24 quality?

25 A. Right.

Page 42 Page 44 1 MR. VOUDOURIS: Objection. 1 A. And I flip through --MR. VOUDOURIS: Objection. 2 A. And there -- I feel may not be very relevant 2 3 Go ahead. 3 for that. A. I flip through these -- a few pictures, 4 Q. (BY MR. THORNBURGH) Did you ask Ethicon's looks -- and the picture does not look very good. 5 lawyers to provide you with better copies of the images 6 that they have or may have in their files? Q. (BY MR. THORNBURGH) So you looked at the A. I -- I didn't. Because I feel that was a long pictures, you looked at the date, but you didn't read 8 time ago and they're -- back to 1980s. And right now is the content; is that fair? A. Uh-huh. 9 2015, is over 30 years. 10 Q. So you didn't consider that in this case, the 10 Q. Because you were rushed? 11 article -- that -- strike that. 11 A. That's fine. 12 12 So you didn't consider this 1980 internal Q. Did you look at and consider any additional 13 internal Ethicon documents other than the 1983 internal 13 Ethicon document in this case because, number one, the 14 date, and number two, because of the poor quality of the memo that we just discussed? 15 A. I didn't. 16 A. Poor quality, right. And that's why I did not 16 MR. THORNBURGH: Take a break? 17 17 pay a lot of attention. I did not use that as a -- or MR. VOUDOURIS: [Nods head.] THE VIDEOGRAPHER: We're off record at 18 studied that for -- for my deposition. 18 19 Q. And so I think I know what document you're 19 10:12 a.m. 20 20 referring to. (Break taken.) 21 THE VIDEOGRAPHER: We're back on record at 21 A. Right. 22 10:20 a.m. 22 Q. Correct me if I -- if I'm wrong, but you're 23 referring to an internal Ethicon document from 1980s 23 Q. (BY MR. THORNBURGH) Doctor, before we went 24 where Ethicon received explanted prolene sutures, off the record, we were talking about the one additional Ethicon document that you reviewed since your report. 25 correct? Page 43 Page 45 A. Correct. 1 And that document was provided to you by Ethicon's 1 2 counsel? Q. And they analyzed those sutures using 3 3 histological methods similar to the methods that were A. Correct. 4 employed by Dr. Iakovlev in this case, correct? Q. And, in fact, all of the internal documents 5 MR. VOUDOURIS: Objection. 5 that you have reviewed have all been provided to you by 6 A. I really -- frankly speaking, I really don't 6 Ethicon, correct? 7 know the detail of this, because first of all, one is, A. Correct. Q. And that document wasn't provided to you until 8 as I mentioned, the time is a long time ago. Two is the 9 after you had testified in three other Ethicon cases, 9 quality of the pictures are very poor. For me, it's 10 difficult to compare what they're saying, you know, what 10 correct? 11 they tried to document. A. I don't remember exactly, but previously, I 12 12 also have received possibly similar documents, but I'm Q. (BY MR. THORNBURGH) Did you read the section 13 in the document called methods? 13 A. So then -- then additionally, I think I really Q. Okay. But the document that we discussed 15 earlier from 1983 --15 don't have time to read all the stuff within this --16 this is pretty thick, based on my memory --16 A. Uh-huh. 17 17 Q. -- which was a histopathology study looking at Q. That's fair. 18 A. -- so I -- I didn't go through. microcracking on explanted prolene sutures, that 19 Q. That's fair. document wasn't provided to you until after you'd 20 A. Right. already testified and reached opinions in the Lewis, Q. So you were -- you felt rushed and didn't have Husky, and Edwards cases, correct? 22 enough time, so you didn't go through the -- the 22 MR. VOUDOURIS: Objection. 23 document --23 A. But based on my memory, it looks like that, 24 A. The detail for these things. 24 yes. 25 25 Q. Okay. Q. (BY MR. THORNBURGH) And that document was Case 2:12-md-02327 Document 2834-4 Wenx Filed 09/19/16 Page 14 of 73 PageID #: 98291 in Zheng, M.D. Page 46 Page 48 1 provided to you after you had already issued and signed 1 MR. VOUDOURIS: Objection; form, 2 your expert report in this case, correct? 2 foundation. 3 3 A. That was only recently, therefore, yes. A. As I mentioned to you a couple of times, one Q. When was that document provided to you? 4 is a very old document. Two is, I don't feel this is 5 A. A couple weeks ago. very much relevant to today's findings, all right. That Q. It was provided to you a couple of weeks ago was 30 years ago. And then three is, the picture, the 6 and you didn't have time to review the text and content quality was very poor, so it's difficult to compare what of the document other than the date and the pictures? is really, you know, what they mean at that time. 9 MR. VOUDOURIS: Objection. Q. (BY MR. THORNBURGH) But if Ethicon has 10 A. I think I have time, but I just didn't pay additional internal documents concerning studies that 11 attention to these, because my opinion is not -- not were performed by Ethicon's scientists of explanted 12 going to rely on those documents, therefore, I didn't go prolene sutures, those would be relevant to you, 13 through. wouldn't they? 14 Q. (BY MR. THORNBURGH) So you had time, you just MR. VOUDOURIS: Objection; form, 15 didn't review it? foundation. 16 A. Yeah. 16 A. Well, that's -- that's why I say based on my 17 Q. And, in fact, regarding all of the -- how many understanding at that time, I don't think this -there's not much relevance, because my focus is on what 18 internal Ethicon documents have you looked at in this 19 case? I have expertise, number one. Number two is, what the 20 A. So if you consider this is one, then the other slides I received and what the clinical information I one is McLean's paper, and I think these are the two I have. Then I render my opinion, okay? 22 have received. 22 Then, plus, as I also mentioned to you, 23 Q. The internal documents that Ethicon provides degradation versus nondegradation. Based on my to you are chosen by Ethicon, correct? observation, there is no evidence -- no histological 25 MR. VOUDOURIS: Objection. evidence for me to say there's any evidence of Page 47 Page 49 A. I did not ask, therefore, you know, I -- yes, 1 degradation. Therefore, I do not consider those 1 2 Dr. Snowden's office sent me these documents. 2 documents I will rely on that are relevant to -- for my (BY MR. THORNBURGH) You meant Mr. Snowden, 3 3 opinion. 4 right? Q. (BY MR. THORNBURGH) So if -- you're telling 5 A. Yeah. I mean, Mr. Snowden, yeah. 5 the ladies and gentlemen of this jury and this judge 6 MR. SNOWDEN: I got a promotion. that if Ethicon has internal documents where their 7 Q. (BY MR. THORNBURGH) Okay. And -scientists concluded that the prolene degraded in vivo, 8 MR. VOUDOURIS: Well, a juris doctor is a you wouldn't find that important or relevant to your 9 doctor, right? case -- to your opinions? 10 Q. (BY MR. THORNBURGH) You had no -- no input in 10 MR. VOUDOURIS: Objection; asked and 11 the types of documents that were provided to you, 11 answered. 12 12 correct? A. I think you're repeating -- repeat -- asking 13 A. No. the same question, and my answer is still the same. And there -- these -- my opinion is mainly rely on the Q. And so you have to rely on Ethicon to provide 15 you with documents that are relevant to this case, material I have received, like the slides, okay? 16 correct? Because I'm a pathologist, okay? Number one. 16 17 17 A. No. I rely on the slides I received and my Number two is, also, I rely on the 18 expertise I have. Then I generate my opinion. That's clinical findings for the -- for this case, right? Then I render my opinion. I do not -- I can't have all

25

19 the main thing I rely on.

20 Q. So are you telling this court and the ladies

and gentlemen of the jury if Ethicon has internal

22 documents discussing Ethicon's scientists' study of

explanted prolene sutures for degradation -- in vivo

degradation, those internal documents would not be

25 important to you in this case?

Q. (BY MR. THORNBURGH) But in all fairness,

So therefore, I don't know how can I evaluate for that.

internal document from Ethicon. As I mentioned, one is, too old. Two is, quality of the picture is not good.

these, like, reading all the materials, you know, within

the field or even internal for that particular case, the

- 1 Doctor, you're a paid expert witness in this case,
- 2 right?
- 3 MR. VOUDOURIS: Objection.
- 4 A. That's right.
- 5 Q. (BY MR. THORNBURGH) You're being paid \$600
- 6 per hour to evaluate Mrs. Corbet's case, right?
- A. Yes.
- 8 Q. And you are being paid \$600 per hour to
- 9 testify today, right?
- 10 A. Yes.
- Q. And you're going to be paid \$600 to testify at
- 12 trial, right?
- MR. VOUDOURIS: Objection.
- 14 A. Yes; if I go.
- Q. (BY MR. THORNBURGH) But you didn't find it
- 16 important enough in this case to review documents
- 17 created and generated by Ethicon scientists before this
- 18 litigation started --
- 19 A. That's --
- 20 Q. -- concerning the issues of degradation found
- 21 in explanted prolene devices or opinions concerning
- 22 pathological findings concerning explanted prolene
- 23 devices, correct?
- MR. VOUDOURIS: Objection; compound, form,
- 25 foundation, and asked and answered.

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 Q. And if they had additional internal Ethicon
 - 2 documents concerning observations and conclusions that
 - 3 explanted prolene devices degraded, it wouldn't matter
 - 4 to you because you don't rely on the internal documents
 - 5 of other Ethicon scientists?
 - MR. VOUDOURIS: Objection; asked and
 - 7 answered.
 - 8 Go ahead.
 - 9 A. As I mentioned to you, I'm a pathologist. I
 - 10 mainly rely on whatever the material I have, such as
 - 11 slides I received for this case. That's the most
 - 12 important thing, all right. Then also, I use routine
 - 13 microscope the pathologists are using every day for
 - 14 their practice to examine what in the slide. Then
 - report candidly about what the finding from the slide.
 - 16 That's my main duty, I think.
 - I have, also, the freedom -- yes, as you
 - 18 say, I'm paid for the deposition or my professional
 - 19 time, but I still -- I'm freedom to choose what is more
 - 20 important or more candid for me to represent, you know,
 - 21 this case, okay. It's not like you -- I'm paid, then
 - 22 you --
 - MR. VOUDOURIS: You've answered -- you've
 - 24 answered his question.
 - 25 THE WITNESS: Okay.

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- 1 A. As I mentioned to you, I think you are
- 2 repeating this question multiple times. I already
- 3 answered that.
- 4 Q. (BY MR. THORNBURGH) But my question was:
- 5 Before this litigation started -- let me strike that.
- 6 Did you -- have you talked to any of
- 7 Ethicon's employees?
- 8 A. I don't think I talked to any Ethicon
- 9 employee.
- 10 Q. So in -- in reaching your opinions today, you
- 11 didn't reach out to any of Ethicon's employees to
- 12 discuss with them what their findings were concerning
- 13 degradation observed in explanted prolene devices?
- MR. VOUDOURIS: Objection. Again, the
- 15 agreement is that this is a Corbet fact specific
- 16 deposition. He was already asked this lines of
- 17 questions in his Husky and Edwards deposition.
- 18 A. And, again --
- MR. VOUDOURIS: So you've already --
- 20 Doctor, you've already addressed those questions in
- 21 prior depositions.
- Q. (BY MR. THORNBURGH) Concerning your opinions
- 23 in this case, Ethicon did provide to you at least one
- 24 internal Ethicon document, right?
- 25 A. Yes.

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 Q. (BY MR. THORNBURGH) Since you issued your
- 2 report in this case, do you have an understanding that
- 3 Dr. Iakovlev's study regarding explanted mesh devices
- 4 has been published in the peer-reviewed articles?
- A. I noticed that.
- 6 Q. Have you published any studies in the
- 7 peer-reviewed articles concerning -- since your last
- 8 deposition -- concerning your examination of explanted
- 9 mesh devices?
- 10 A. Not yet.
- 11 Q. Are you planning to?
- 12 A. Yes. We -- because this -- I also feel this
- 13 is a needed within the pathology -- surgical pathology
- 14 field. Just like Dr. Smith's paper, they found
- 15 approximately 50 percent of the cases not being
- 16 processed properly. Therefore, there is a need in this
- 17 field as a pathologist.

- 18 If they -- when they receive these
- 9 specimen, they should know how to handle them in a
- 20 standard way rather than just a random way. I think
- 21 that's the reason we are planning to do.
 - Q. So let me try to understand exactly. Are you
- 23 planning on writing a report -- or a publication similar
- 24 to the Smith publication, or are you planning on
- 25 publishing your opinions concerning your evaluation of

Page 54 1 explanted mesh devices?

- 2 MR. VOUDOURIS: Objection.
- 3 A. No, we are planning to just to provide
- 4 information to the field, or to the general
- 5 pathologists, let them be aware these specimens become
- 6 more common, although they consider as their foreign
- 7 body kind of material and people usually pay less
- 8 attention for those specimens.
- 9 But these days, because of the importance
- 10 in the field, then people -- pathologists should be
- 11 aware how to handle these specimens, how to describe or
- 12 what they should look for in the microscope in their
- 13 practice. That's the purpose we are planning to do.
- 14 Q. (BY MR. THORNBURGH) Okay.
- A. I'm not planning to do -- to -- specifically
- 16 to address what Iakovlev's opinion and -- and my
- 17 opinion. This is not relevant at all.
- Q. Okay. So just to summarize, because that was
- 19 a lot of information --
- 20 A. Right, right.
- Q. -- since your report, Dr. Iakovlev has
- 22 published his opinions concerning his observations of
- 23 explanted polypropylene, including TVT, devices, in
- 24 peer-reviewed publications, correct?
- A. In the -- in the one article peer reviewed,

- 1 opinion.
- Q. (BY MR. THORNBURGH) Okay. So let me make

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- 3 sure I understand that correctly. Number one, you're
- 4 not suggesting in any way that Dr. Iakovlev somehow
- 5 had -- had some -- strike that.
- 6 You're not suggesting that Dr. Iakovlev in
- 7 this case, in publishing his -- his articles in the
- 8 peer-reviewed journals that he published those articles,
- 9 had some sort of input on who reviewed his article, are
- 10 you?
- 11 A. This is a common process. I'm not sure what
- 12 they have done in the process, but this is the common
- 13 process. Every author or authors when they submit
- 14 articles, they have a chance to suggest who will be the
- 15 reviewers. Then, in many journals, they will follow
- 16 these suggestions to pick up the reviewers.
- Q. Okay. But you're not suggesting that that --
- 18 you don't have any basis or --
- 19 A. No.
- Q. -- information to suggest that happened with
- 21 Dr. Iakovlev's article, right?
- A. That's why I say this in general.
- O. So in general, when -- so let's talk about
- that. In general, it's your understanding from your
- 25 experience working in -- as a -- I think you said chief

- 1 yes.
- Q. And what does it mean to be peer reviewed?
- A. Peer reviewed can have many meaning. That
- 4 means within the field. Then the editor of the journal
- 5 will ask for one, two, or three reviewers to review
- 6 what's the information in it.
- 7 Q. And that's because you want to make sure that
- 8 the peer-reviewed allows for the publication of more
- ⁹ reliable articles because the peers, your peers, review
- 10 it and are critical when they review it, and determine
- 11 whether or not it should be published, correct?
- MR. VOUDOURIS: Object to form.
- A. It's not necessary for that. Because I served
- 14 as a co-chief editor for one of the professional
- 15 journals recently. And we know within this process the
- authors are encouraged to submit the reviewer's name,
- 17 because in every specialties, they -- they have some
- 18 people they know are doing similar work. So therefore,
- 19 there is a preference by authors who should review their
- 20 articles. That's the process.
- Therefore, this kind of process, although
- 22 is still considered as a peer review, but it's not
- 23 necessary all peer-reviewed articles. They are
- 24 scientifically sound or they are just correct for their
- 25 opinion. It still represent a group of the author's

- 1 editor?
- 2 A. Yes.
- 3 Q. -- co-chief editor in a peer-reviewed journal
- 4 that, unfortunately, publications -- articles can get
- 5 published through a peer-reviewed process when -- when
- 6 the author actually has some influence on who reviews
- 7 the publication?
- 8 MR. VOUDOURIS: Objection; form.
- 9 A. Yes, this is correct.
- Q. (BY MR. THORNBURGH) And that would include,
- 11 for example, if Ethicon's key opinion leaders want --
- 12 wanted to publish their studies in a peer-reviewed
- 13 publication under -- based on your experience, they
- 14 could have some influence or input into who actually
- 15 reviews their article before it gets published in the
- 16 journal, correct?
- MR. VOUDOURIS: Objection; form,
- 18 foundation.
- 19 A. Author has this choice. However, journal
- 20 editors has their own decision who should be asked for
- 21 review. So these are the dual ways. It's not only one
- 22 way.
- 23 Q. (BY MR. THORNBURGH) Journal editors such as
- 24 yourself?
- 25 A. Right.

Page 58 Page 60 1 Q. Who's a paid expert for Ethicon? 1 spend much time. Let me just -- let me try to see if I MR. VOUDOURIS: Objection. 2 2 understand just briefly. So if I did an experiment, for 3 A. What do you mean? Paid for -- expert for --3 example, and I experimented and I had one sample -- N Q. (BY MR. THORNBURGH) You're an expert for 4 4 equals one, right? 5 Ethicon in the litigation, right? A. Right. 6 A. The journal -- my journals, they -- we do not Q. If I had one sample and I reached a conclusion based on that one sample and sent it to you to be have any publications related to mesh yet so far. Q. But in some circumstances, the authors have published in an article, would you have a problem with publishing an article that reaches conclusions based on 9 input on who reviews their publications and editors can 10 veto a decision to have reviewers -- certain reviewers an experiment that included only one sample? 11 review an author's publication. 11 MR. VOUDOURIS: Objection; form and 12 foundation. 12 And in the current situation, you're an 13 editor for a peer review publication and also an expert 13 A. Usually, that will be rejected. I don't think 14 for Ethicon? many journals will accept based on a single sample, but 15 MR. VOUDOURIS: Objection; form, we do have interesting case report. Case report, that's 16 foundation, asked and answered, and very compound. different issue. 17 A. Yeah. I think that this is not 17 Q. (BY MR. THORNBURGH) So -- and -- so for a 18 really relevant. peer-review publication, a study with N equals 1 -- I 19 Q. (BY MR. THORNBURGH) I'll withdraw the think I've read somewhere that you want to have at least three samples in an experiment in order for it to be 20 question. 21 considered reliable. Is that accurate? A. Yeah. Not really relevant. 22 Q. This is a new position that you have, though, 22 A. No. 23 23 as a co-editor? MR. VOUDOURIS: Objection; form, 24 A. It's been for two years. foundation. 25 MR. THORNBURGH: I assume I can ask some You've answered his question. Page 59 Page 61 1 questions about that if he wasn't a co-editor in the THE WITNESS: Yeah. 1 A. No. prior cases? 3 Q. (BY MR. THORNBURGH) How's it not? I'm MR. VOUDOURIS: You can ask. 4 trying -- I'm just trying to understand. Q. (BY MR. THORNBURGH) What -- what peer-reviewed publication are you a co-editor for? A. No. This is a -- like a publication -- or A. The journal name is American Journal of 6 receive a manuscript to be considered for publication is 7 Clinical and Experimental Obstetrics and Gynecology. a -- is a long process. It's not that simple. I cannot 8 Q. What do you mean by "experimental obstetrics use one minute or two minutes to explain to you the 9 and gynecology"? entire process. I think this is also not relevant for A. That means within the ob -- obstetrics and 10 10 this case too. 11 gynecology field, all the studies related to the 11 Q. Fair enough. 12 12 clinical side as well as experimental side, then we will Do you have an updated curriculum vitae? 13 13 accept if they have a good quality. MR. VOUDOURIS: It's on Exhibit 2. 14 Q. In other words, if they apply some sort of --A. Yes. I submitted that and also included in 15 strike that. the thumb drive. 16 16 Q. (BY MR. THORNBURGH) So in -- for preparing In other words, if their method was 17 reliable? for this deposition, approximately how many hours --18 strike that. MR. VOUDOURIS: Objection. 19 19 A. We have to review. That's why -- depending on In preparing for this case and 20 the quality and what kind of study, what kind of method re-reviewing the case, looking at the new articles, 21 they use, study design, hypothesis, then the contents, getting ready for this deposition, approximately how 22 then the results, then all these, you know, relevant many hours do you have invested in this case since your

24 think you want to understand.

25

23 informations. That's a complicated process. I don't

Q. (BY MR. THORNBURGH) No; I'm not going to

MR. VOUDOURIS: Objection; asked and

invoice of last year?

23

24

25 answered.

- 1 MR. THORNBURGH: I don't think I asked how
- 2 many hours.
- 3 A. I didn't estimate exactly, but I think
- 4 approximately 15 hours.
- 5 Q. (BY MR. THORNBURGH) 15?
- 6 A. Approximately.
- 7 Q. And it looks like, according to the invoice
- 8 that was produced on Exhibit Number 2, which we'll maybe
- 9 mark later on as a separate exhibit, you've been paid in
- 10 this case so far approximately \$29,400. Does that sound
- 11 about accurate?
- 12 A. That sounds accurate.
- Q. And since that invoice, you've worked on this
- 14 case for approximately 15 additional hours?
- A. Right. Because it's only recently I've been
- 16 noticed, you know, deposition starts.
- Q. And the deposition notice is actually marked
- 18 as Exhibit Number 1. If you can grab Exhibit Number 1
- 19 real quick. When was that notice sent to you -- or I'm
- 20 sorry, strike that.
- 21 When was that notice -- what's the date of
- 22 that notice?
- A. I don't remember exactly what the date the
- 24 notice. I think a couple -- starting from maybe a
- 25 couple of months ago, I -- Andy sent me a note saying --

- A. This is the notice for today's deposition,
- 2 right?
- 3 Q. Yes.
- 4 A. And -- yeah, I mean, I guess this -- if you're
- 5 asking -- you already know the answer. I don't know why

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- 6 you're asking me this question.
- Q. Because I get to ask these -- these questions.
- 8 For -- for good or for bad, I get to ask these
- 9 questions.
- So the date is November 13th, 2015. So
- 11 the 15 additional hours that you put in this case since
- the invoice of last year, would that have all happened
- 13 after November 13th of 2015?
- 14 A. Yeah. Mainly -- majority of the -- the work
- 15 has been done, that's these, you know, days, basically.
- 16 That's why I say some of these documents I really don't
- 17 have time to go through.
- Q. So the 15 hours is after November --
- 19 November 13th, 2015, right?
- 20 A. That's -- that's fair.
- 21 MR. VOUDOURIS: Objection.
- A. In the -- yeah, in the last several days.
- Q. (BY MR. THORNBURGH) Okay. And how much
- 24 time -- how much of the 15 hours was spent on meeting
- with Ethicon's attorneys to prepare for this deposition?

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- 1 asking me what is available dates, possible dates and --
- 2 MR. VOUDOURIS: Doctor, listen to his
- 3 question.
- 4 Q. (BY MR. THORNBURGH) Yeah, my -- my
- 5 question --
- 6 MR. VOUDOURIS: He asked -- he asked a
- 7 different question.
- 8 Q. (BY MR. THORNBURGH) Yeah. My question is
- 9 simply -- because you indicated you had -- since your
- 10 invoice of last year, you had worked for about 15
- 11 additional hours on this case, and you said that you
- 12 began that work after you received the deposition
- 13 notice. And so my question to you was, well, what's the
- 14 date of the deposition notice?
- MR. VOUDOURIS: I think he was confused by
- 16 your earlier question.
- A. I don't -- don't remember when Andy --
- 18 Q. (BY MR. THORNBURGH) If you just look at
- 19 page --
- 20 MR. VOUDOURIS: Doctor --
- Q. (BY MR. THORNBURGH) If you look at page 2 of
- $\,$ 22 $\,$ the deposition notice, it says November 13th, 2015. Do
- 23 you see that on Exhibit 1, page 2? Do you need help?
- 24 Right there on the bottom -- right there, see the last
- 25 notation on that page, it says date?

- A. I think a couple of hours, you know, we met
- ² for that.

10

13

- Q. Did you meet one -- one time, two times, more
- 4 than two times? How many times did you meet in
- 5 preparation for this deposition?
- A. Last -- yeah, we have twice.
- Q. Okay. So the first time you met was when?
- 8 A. That was last week sometime. I don't remember
- 9 exactly. But then also yesterday.
 - Q. Okay. So the first meeting that you had in
- 11 preparation for this deposition last week, how long did
- 12 that meeting last?
 - A. Probably about one hour, one and a half hour.
- Q. Okay. And then you indicated, I think, that
- 15 you also met again yesterday?
- 16 A. Yesterday.
- Q. And how long did you meet yesterday in
- 18 preparation for this deposition?
 - A. Similar time.
- Q. So one to one and a half hours?
- 21 A. Right.
- Q. So you've -- you've met and prepared -- you
- 23 met with Ethicon's lawyers in preparation for this
- deposition for approximately two to three hours?
- 25 A. Yes.

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	Page 66		Page 68
1	Q. So if you worked 15 hours and you worked	1	is I don't rely on the expert witness as my main
2	and you spent two to three hours preparing with	2	income, no.
3	Ethicon's lawyers, what was the rest of the time	3	Q. (BY MR. THORNBURGH) That wasn't my question.
4	dedicated to?	4	A. I know. That's why I say I answered I
5	A. Reading, write, and review my report and	5	don't remember exactly.
6	refresh my mind what plaintiff's expert has said, just	6	Q. Okay. But I'm entitled to a fair estimation.
7	Dr. Iakovlev's report in the Exhibition [sic] Number 5.	7	So do you think it's been about 80,000 to \$100,000?
8	So those are the time I spent.	8	MR. VOUDOURIS: Objection.
9	Q. Have you read since	9	A. Maybe after all these cases. Each case is
10	MR. VOUDOURIS: Dan, I'm sorry. Do you	10	about \$25,000, something like that. I but I don't
11	want to go off the record for a second?	11	quote exactly, okay? This is the rough estimation.
12	MR. THORNBURGH: Sure.	12	Q. (BY MR. THORNBURGH) Okay. And so you've
13	THE VIDEOGRAPHER: We're off we're off	13	you've testified in the Husky, Edwards, and Lewis cases,
14	record at 10:52 a.m.	14	correct?
15	(Break taken.)	15	A. Correct.
16	THE VIDEOGRAPHER: We're back on record at	16	Q. And you're testifying in this case. So is
17	10:57 a.m., beginning of Tape 2.	17	that about \$100,000?
18	Q. (BY MR. THORNBURGH) In preparation for	18	MR. VOUDOURIS: Objection.
19	your strike that.	19	A. I'm not sure.
20	Have you read or reviewed any additional	20	Q. (BY MR. THORNBURGH) Approximately? If
21	depositions in this case in preparation for your expert		it's if it's \$25,000 per case?
22	opinion in preparation for your deposition?	22	MR. VOUDOURIS: Objection; asked and
23	A. I read Dr. Smith's deposition.		answered.
24	Q. When did you read Dr. Smith's deposition?	24	A. I'm not sure. That's why I said, okay?
25	A. I think the the first time was was last	25	Q. (BY MR. THORNBURGH) Have you consulted with
	71. I tillik tile tile first tille was was fast		Q. (BT MR. ITTORADOROTI) Thave you consulted with
	P (7		
	Page 67		Page 69
1	year before the this expert report was prepared.	1	Page 69 Ethicon on any additional cases other than the four that
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	year before the this expert report was prepared.		Ethicon on any additional cases other than the four that
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Page 70 Page 72 1 Q. (BY MR. THORNBURGH) And I'm not going to go 1 for publication. That's for sure. But I do have plan, 2 there. I'm just trying to find out if you've been 2 together with my students, to summarize the mesh 3 disclosed as an expert in any other cases for -- for -specimen related to the surgical pathology practice. 4 as an expert for Ethicon. Q. And that's what we discussed earlier? A. For Ethicon? I have -- whatever the case I A. Correct. 6 received, I always disclosed what I have done. That's Q. Not a -- an article regarding your findings as 7 for sure. a pathologist under the microscope, but rather, Q. I -- let me -- so let me just try and clarify. recommendations to the community about doing microscopic examinations of explanted mesh devices? 9 So what disclosure means --MR. VOUDOURIS: Dan, can I help you? I 10 10 A. Correct. 11 don't believe he's --11 Q. And when do you plan on publishing that? Q. (BY MR. THORNBURGH) Have you been identified 12 12 A. We don't know because everybody's so busy, 13 as an expert witness -lots of things going on. So as soon as we have 14 MR. THORNBURGH: Go ahead. 14 adequate -- manage to be ready, then we are ready. MR. VOUDOURIS: Let me help you. I don't 15 15 Q. Is the manu -- has the manu -- strike that. 16 believe he's --16 Have you began to write the article? 17 17 MR. THORNBURGH: You know the answer? A. Not yet. We're still collecting the data. 18 MR. VOUDOURIS: Yeah. 18 Q. Okay. So there's no draft of any --19 MR. THORNBURGH: Okay. 19 A. No. MR. VOUDOURIS: I don't believe he's been 20 Q. -- form? 20 disclosed in other cases other than the ones he's 21 And so right now, you and your students 21 22 are collecting data? 22 mentioned. 23 Q. (BY MR. THORNBURGH) Okay. Have you consulted 23 A. Correct. with any other mesh manufacturers? Q. What types of data are you collecting? A. No. 25 A. It's explanted mesh material. 25 Page 71 Page 73 Q. Since issuing your expert report, have you 1 Q. So are you -published any articles in any peer-review journals? A. Mesh specimens. A. Not for mesh. Yes, I have -- every year I 3 Q. Are you actually collecting mesh specimens? 4 have more than 10 papers published. A. No. We only examine the slides already Q. That was going to be my next question. So I 5 existed or the samples received in the department of 6 think the answer is, yes, you've published since you pathology in the University of Arizona. 7 issued your expert report. Is that fair? Q. All right. So let me just try to understand 8 8 this. So you're collecting data, and the data that A. Yes. Q. Which you -- I assume you've -- is included in you're collecting are slides that are available --10 your updated CV, which is attached as Exhibit 2? pathology slides that are available at Arizona 11 11 University -- Yes. You can -- you can see it. 12 12 Q. And none of those like -- like prior to the --A. Uh-huh. 13 this -- like prior to your expert report that you issued 13 Q. -- or University of Arizona. But you have no 14 in this case -- strike that. intention of analyzing those slides and publishing your 15 findings -- your pathological findings concerning that None of the new publications that you've 16 analysis? 16 authored or coauthored that have been published in 17 peer-reviewed articles since your expert report relate MR. VOUDOURIS: Objection; form. 18 Q. (BY MR. THORNBURGH) Because I thought earlier 18 to mesh, correct? 19 A. Correct. you testified that you had no intention of -- I think I 20 Q. And none relate to the TVT product? understand. So you have no intention of publishing your findings based on your review of mesh devices that A. Correct. Q. And you have no intention of publishing in 22 you've looked at in the context of this litigation? 23 peer-reviewed articles concerning your work as an expert 23 A. No, I'm not planning to do that, because this 24 in these cases, right? 24 is --

25

A. I don't have intention to use these material

25

MR. VOUDOURIS: You answered his question.

Case 2:12-md-02327 Document 2834-4 Filed 09/19/16 Page 21 of 73 PageID #: 98298 Wenxin Zheng, M.B. Page 74 Page 76 1 A. Yeah, I already answer this question. 1 reports. 2 Q. (BY MR. THORNBURGH) So -- so do you plan on Q. (BY MR. THORNBURGH) And for the majority of 3 publishing your findings from your review of explanted 3 those cases that you sign out the reports that you've 4 pathology specimens that you're currently collecting 4 done in the past -- and I think you described this from the University of Arizona? earlier when we talked about the Smith article, that 6 MR. VOUDOURIS: Objection; form. 6 most pathologists report on their macroscopic 7 observations. Is that accurate? A. As I say, we are planning to publish or 8 summarize the data regarding mesh specimen received in A. Some of them, yes. 9 the past five years in the University of Arizona, which Q. Okay. And so of the 100 -- of the majority of 10 may be useful for the surgical pathology field. How to the 150 that you've looked at in the past and have 11 handle the specimen correctly, how to describe -- or issued -- or signed out on the reports, was that based 12 what the kind of features that a pathologist should look on macroscopic or microscopic observations? 13 for. Those are the information will be useful for the 13 A. I don't know how many they are macroscopic 14 field. only, but if macroscopic only, we will just record a 15 number. And all the findings will be based on Q. (BY MR. THORNBURGH) Okay. So when you say 16 you're going to summarize the data, you're talking about microscopic findings. your analysis of the pathology material at the 17 Q. For the 150 at Arizona, you wouldn't have to University of Arizona, right? 18 necessarily go -- strike that. 19 MR. VOUDOURIS: Objection; form. 19 When you were working for the University 20 A. Yes; based on the pathology material there. of Arizona as a pathologist and you were signing off on 21 Q. (BY MR. THORNBURGH) And, currently, you're the reports, is it fair to say the majority of those 22 collecting the data? reports that you signed off on were based on a 23 A. Currently, we are collecting the data. 23 macroscopic observation of the explant material? 24 Q. Have you determined how many explant specimens 24 25 are available at Arizona for the five-year period? 25 MR. VOUDOURIS: Objection. Page 75 Page 77 A. Mainly -- majority of such cases based on, A. Yeah. We estimated the total -- we did a 2 they do have microscopic slides prepared. search after our approval. We have a total of Q. (BY MR. THORNBURGH) I know they may have --³ approximately 150 cases. 4 so they have microscopic slides prepared. Does that Q. Total of 158 cases? 5 A. -50, 1-5-0. 5 mean they were actually analyzed by you or another Q. 150 cases. And this is a single institution pathologist microscopically, or were the reports signed 7 at the University of Arizona? off based on a macroscopic observation? 8 MR. VOUDOURIS: Objection. A. Correct. 9 Q. Is it the pathology department at the 9 A. Majority of them based on both macroscopic as 10 University of Arizona? 10 well as microscopic. 11 11 Q. (BY MR. THORNBURGH) So is it fair to say --A. Yes. 12 Q. And are you a pathologist at the University of 12 is -- is it your understanding that, like the Smith 13 Arizona? article, perhaps, that 50 percent were microscopic and 14 A. I was there for 10 years. 50 percent were macroscopic? 15 15 Q. Are you still there? MR. VOUDOURIS: Objection. 16 16 A. Things are different, because our institution, A. Recently, starting from July 1st of this year, 17 I relocate to UT Southwestern. things -- starting from, I think, two to three years 18 ago, we have noticed those situations in the entire Q. And are these pathology -- strike that.

23

24

25

examination.

those specimens -- have -- strike that.

So the pathology material that is being

Have you previously analyzed those

specimens as an employee of University of Arizona?

MR. VOUDOURIS: Objection.

collected, 150 or so that have been identified, are

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Q. (BY MR. THORNBURGH) Okay. So a lot of

Then -- since then, every specimen, if the

medical field, so therefore, I was asked to provide

specimen -- the size is larger than two centimeters, then half of them will be processed for microscopic

standard protocol how to handle these specimen.

- 1 information. And this is why your -- why you decided to
- 2 do an article -- publish an article on it and working
- 3 with your students. So let me just try to figure out.
- 4 About two to three years ago, you drafted
- 5 the protocol on how to handle specimens?
- A. Correct.
- Q. Okay. Have you produced that protocol in anyof these cases yet?
- 9 A. We did not publish, because it's like internal
- 10 guideline for our pathologists. And also, we have -- in
- 11 the University of Arizona, we have risk management
- 12 office. They were involved for some of those cases,
- 13 because they -- it's labeled as a legal case, so
- 14 therefore, they have to save the -- some of the specimen
- 15 into the risk management office.
- Then, that cause lots of problem, because
- 17 the pathologist department -- pathology department is
- 18 responsible to release pathological finding. And if
- 19 they are -- they want to help -- hold these cases, then
- 20 we are not able to issue the report. So therefore, we
- 21 all came together, then came out as a general consented
- 22 guideline. I'm the main person to provide this
- 23 guideline --
- 24 Q. Okay.
- A. -- because I was -- I was the GYN pathologist

- 1 pathology specimens that were received at the University
- 2 of Arizona because some of those cases were labeled as
- 3 legal -- legal cases, correct?
- 4 A. Yes.
- Q. So the specimen goes to the risk management
- 6 office at that point?
 - MR. VOUDOURIS: Objection. If you know.
- 8 A. Yes. Some of them, they go, then that's why I
- 9 say because these are conflicts. If risk management has
- 10 all the specimens, then department of pathology has no
- 11 specimen, then no report is going to be issued.
- 12 Therefore, the clinician is concerned, and then
- pathology department also is concerned.
- And -- because they send to us and we
- 5 don't have report, therefore clinician, risk management
- 16 office, and pathologist all come together and have a
- 17 consensus meeting how to handle these specimens. Then I
- 18 generate this guideline.
- Q. (BY MR. THORNBURGH) Okay. And so did the
- 20 guideline somehow -- I assume based on what I think I
- 21 understand from your testimony, the guideline
- 22 established that half of the specimen would be divided
- 23 and kept at the University of Arizona risk management
- 24 department, and then the other half would be analyzed by
- you or other pathologists?

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- 1 there.
- 2 Q. Okay. So my question was: Has that written
- 3 protocol been produced in any of the cases -- litigation
- 4 cases to date?
- 5 A. It's -- all these litigation cases today is
- 6 not from University of Arizona, therefore, it's not
- 7 relevant.
- 8 MR. THORNBURGH: We want -- I want a copy
- 9 of the protocol from the University of Arizona that he
- 10 drafted and -- which serves as a protocol for how to
- 11 handle mesh specimen explants.
- MR. VOUDOURIS: I don't know if I have any
- 13 control over what the internal department at the
- 14 University of Arizona says and whether they're IRB and
- 15 HIPAA implications --
- 16 THE WITNESS: Right.
- MR. VOUDOURIS: -- so I can't answer that
- 18 question.
- 19 MR. THORNBURGH: I'll send a follow-up
- 20 e-mail requesting it.
- Q. (BY MR. THORNBURGH) And just to follow up on
- 22 some other things that you said, you were the -- sorry.
- 23 Strike that.
- So you test -- just testified that the
- 25 risk management office was involved in some of the

- Page 81 MR. VOUDOURIS: Objection.
- 2 Q. (BY MR. THORNBURGH) And that was for the
- 3 legal -- the legal cases?
- 4 MR. VOUDOURIS: Objection.
- A. Yeah, yeah. If you really want to know the
- 6 content, I think because I'm the person write this one,
- 7 I can tell you the basic components, all right? The
- 8 basic thing is if the specimen is larger than two
- 9 centimeter in size, all right, then we will cut half for
- 10 histological examination process. Then the remaining
- 11 half will be saved in the formalin and will be delivered
- 12 to the high risk -- or risk management office, number
- 13 one.
- Q. (BY MR. THORNBURGH) To -- sorry, go ahead.
- 15 A. Number two, if the specimen is smaller than
- 16 two centimeter in size, then no histological section
- will be done because it's for legal purposes. Then the
- 18 entire specimen will be delivered to the risk management
- 19 office.
- Q. Okay. So I think I understand all -- so let
- 21 me just figure it out, just make sure I understand it.
- 22 And you're -- you were the person that oversaw this
- 23 change in the process at the University of Arizona,
- 24 right?
- 25 A. Correct.

Page 82 Page 84 1 Q. And that was two to three years ago? 1 mesh was explanted and sent to the pathology department 2 A. Yes. 2 of the university that was greater than two centimeters, 3 3 and I sent a preservation letter to preserve that Q. And that was while you were serving as an 4 expert for Ethicon? 4 evidence for purposes of litigation, you would first A. No. I don't think that's the -- that's the divide that specimen and keep it and analyze it at the 6 reason. Because I -- I'm the --University of Arizona and send the other half for Q. That wasn't -- my question wasn't, was that litigation -- for -- to the risk management for hold? 8 the reason? My question to you was: When the protocol MR. VOUDOURIS: Hold on. changed, based on your recommendations, you were an 9 Q. (BY MR. THORNBURGH) Right? 10 10 expert for Ethicon? MR. VOUDOURIS: Hold on. I gave you 11 MR. VOUDOURIS: Objection; form. leeway to ask questions about this. This has absolutely 12 nothing to do with the fact specifics of Corbet. You A. That's not related, because --13 have asked tons of questions about it that has nothing Q. (BY MR. THORNBURGH) It's a yes-or-no 14 question, though. to do with Corbet. And I --15 15 A. Yeah. MR. THORNBURGH: He's -- he's offering 16 Q. I mean, were you an expert at the time for this testimony. 17 Ethicon? 17 MR. VOUDOURIS: Well, I'm telling the 18 A. At the time, I was, but this was not the 18 doctor --19 reason because I'm the expert for Ethicon, then I will 19 MR. THORNBURGH: I'm just following up on 20 provide -- volunteer and provide this guideline. No. 20 it. 21 MR. VOUDOURIS: This has nothing to do 21 Because I am -- I was the chief of the GYN pathology 22 there, then in handling all the GYN specimen, including with Corbet. He's asked -- he's answered plenty of 23 mesh specimen -questions on this topic, so let's get to the fact 24 Q. Okay. specifics of Corbet. 25 25 MR. THORNBURGH: I mean, I think, in all A. -- okay? Page 83 Page 85 Q. Hold on. So my question was simply: At that 1 fairness, he -- he offered that -- that -- that 1 2 time, when you changed the protocol, you were an expert 2 information voluntarily. I get to follow up on it and of -- for Ethicon? That's my only question. 3 say, you know, if I send -- if I -- if my -- if I send a MR. VOUDOURIS: Objection; form, 4 preservation letter to the University of Arizona for a 4 foundation. specimen that was explanted from my client and there's 6 Q. (BY MR. THORNBURGH) So the answer to that 6 two centimeters, I don't get the full explant to be 7 question is yes, right? analyzed? 8 A. Yes. 8 MR. VOUDOURIS: It has nothing to do with 9 MR. VOUDOURIS: Objection. the fact --10 Q. (BY MR. THORNBURGH) And so -- so if I had a 10 MR. THORNBURGH: I think that's important. 11 legal case, all right, my client had a mesh specimen of 11 MR. VOUDOURIS: It has nothing to do with 12 two centimeters that was available at the University of 12 the fact specifics of Corbet. 13 13 Arizona, and I sent a request for preservation of the MR. SNOWDEN: If you want to pull out an 14 two centimeter sample -- explant sample so that it could Ethicon preservation notice which tells the hospital to 15 be evaluated for purposes of litigation, the protocol follow their standard procedures, why don't you show him 16 that you established would actually send for litigation 16 that? 17 17 purposes only one centimeter to be analyzed? MR. THORNBURGH: That's something we'll 18 A. If it -take up at a later time. 19 MR. VOUDOURIS: Hold on. 19 Q. (BY MR. THORNBURGH) How much -- in 20 Q. (BY MR. THORNBURGH) Let me -- let me -- let Mrs. Corbet's case, how much mesh was explanted? me -- let me ask again. I'll withdraw that line of 21 A. I think I have a gross description about the 21 22 questioning and let me get it down. 22 slides and the specimen I received.

23

23

So two to three years ago, as an expert

24 for Ethicon, you changed the protocol such that if I had

25 a case -- I had -- I had -- I represented a client whose

Yes. I said I received the following

material labeled as Kathryn Corbet. And then date of

surgery, that was February 19, 19 -- 2013. And the

- 1 first batch includes three H&E slides and two unstained2 slides.
- 3 All right. Then the slides labeled as A1,
- 4 B1, and C1. Then slide C1 represent ex -- excised mesh.
- 5 Now, A1 and B1 were from bladder biopsies. The second
- 6 batch of the slides include five H&E and four
- 7 corresponding S-100 staining with was one positive
- 8 control, and the four masson trichrome stained slides
- 9 and one positive control. So those are the material I
- 10 received.
- Q. Okay. And that's the material that you
- 12 received from -- after Mrs. Corbet had her explant --
- 13 A. Correct.
- Q. -- from -- at the University of Pennsylvania
- 15 Health System?
- 16 A. Yes.
- Q. Do -- do you know anybody -- any -- any
- 18 pathologist who work at the University of Pennsylvania
- 19 Health System?
- 20 A. Personally, I don't know any pathologist
- 21 there, but they must have large amount of pathologists
- 22 there.
- MR. VOUDOURIS: He just asked you if you
- 24 knew anyone at the University of Pennsylvania pathology
- 25 department.

- ained 1 present will be recorded. Therefore, they're
 - 2 reviewing -- one pathologist will present his or her
 - 3 cases. Then the remaining pathologists will render
 - 4 their opinion, either agree or provide different
 - 5 interpretations, then, finally, people will get a
 - 6 consent.
 - Q. (BY MR. THORNBURGH) Have you participated in

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- 8 a consensus conference before?
- MR. VOUDOURIS: Objection.
- Q. (BY MR. THORNBURGH) Since -- how about since
- 11 your last deposition, have you participated in a
- 12 consensus?
- 13 A. Every week, we have that.
- 14 Q. Have you participated, since your last
- 15 deposition, in a consensus conference case regarding a
- 16 mesh explant?
- 17 MR. VOUDOURIS: Objection.
- A. There -- there is no -- no need for mesh to be
- 19 considered for a consensus, because this is not
- 20 considered as a complicated case or difficult case.
- 21 Q. (BY MR. THORNBURGH) That wasn't my question,
- 22 though. My question was --
- MR. THORNBURGH: So move to strike.
 - Q. (BY MR. THORNBURGH) My question was pretty
- 25 simple. As -- since your deposition, have you served on

- A. Yeah, personally, I don't know anyone as a --
- 2 as a collaborator or -- or friend, no.
- 3 Q. (BY MR. THORNBURGH) And we're going to get
- 4 into the -- the records here pretty soon, but -- in
- 5 greater detail. But do you know what a consensus --
- 6 consensus conference case is?
- 7 A. Consensus conference means a group of
- 8 pathologists read certain case together, get a consented
- 9 opinion. That's a consensus conference.
- Q. And do you do a consensus conference -- or did
- 11 you do a consensus conference at the University of
- 12 Arizona?
- MR. VOUDOURIS: Objection.
- A. We do -- we do all the time, but mainly for
- 15 cancer cases as well as for difficult cases or unusual
- 16 cases.
- Q. (BY MR. THORNBURGH) And when -- in your
- 18 experience when these consensus conferences take place,
- 19 is there documentation created that discusses the
- 20 consensus reached by the pathologists who reviewed the
- 21 pathology material separate from the pathology report
- 22 that's signed by the pathologist?
- 23 MR. VOUDOURIS: Objection.
- A. Okay. Within the consensus meeting,
- 25 generally, there is a sheet. All the pathologists

- 1 a consensus panel concerning the analysis of explanted
- 2 mesh material?
- 3 MR. VOUDOURIS: Objection; asked and
- 4 answered.
- 5 MR. THORNBURGH: And the answer is yes or
- 6 no. I mean, he -- he didn't answer the question.
- 7 A. I answered no.
- 8 MR. VOUDOURIS: He said there's no need
- 9 to.
- 10 A. I also give you the reason why no, because
- 11 there is no reason to have any hospital -- so far, based
- 12 on my understanding -- to review the mesh material in
- 13 the consensus conference. I can guarantee you.
- Q. (BY MR. THORNBURGH) It appears from -- from
- 15 your --
- 16 A. Except for some complications or for other
- 17 reasons. In general, there is no need at all.
- Q. Does it appear from your review of the
- 9 pathology report from Mrs. Corbet's explant that there
- 20 was a consensus conference concerning her explant
- 21 material?
- A. I don't think I have written something like
- 23 that. Can you show me where it is? Or we may have some
- 24 misunderstanding there.
- 25 (Sotto voce conversation.)

Page 90 Page 92 1 (Exhibit Number 6 was marked.) 1 THE WITNESS: Okay. Q. I'm going to mark as Exhibit Number 6 and Q. (BY MR. THORNBURGH) Do you see where it says 2 consensus conference case? 3 we're going to talk about this throughout the A. I saw that. 4 deposition, but this -- I'm handing you Exhibit Number 6, which is from the pathology department at the Q. Would that indicate to you that the mesh or 6 other explant tissue material that was removed from Pennsylvania hospital. There you go. 7 Mrs. Corbet's body was looked at by multiple MR. VOUDOURIS: Do you have an extra copy? 8 MR. THORNBURGH: I'm sorry, Counsel. I pathologists during a consensus conference? MR. VOUDOURIS: Objection; form, 9 didn't do that on purpose. 10 (Witness reviewed document.) 10 foundation. 11 Q. (BY MR. THORNBURGH) And if you turn in 11 A. Here, consensus conference case usually 12 Exhibit Number 6, if you turn to Bates number ending in 12 indicate part of the specimen as being reviewed in -08. Are you there? the -- in this consensus meeting, okay? Part of the 14 A. Yes. specimen. All right. It's not a very good way to 15 Q. And do you understand -- you understand that record in the very vague way, say consensus conference 16 you're looking at the -- do you recognize that you're 16 case. 17 17 looking at the pathology --Typically, people will say which specimen 18 A. The pathology report from the University of has been reviewed in that consensus meeting, and then 19 Pennsylvania Health System. what kind of opinion or consensus opinion has been Q. Okay. And you see -reached? That's a typical way of a more -- it's a 20 21 better way to describe, rather than just say consensus A. You highlighted specimen C, right? 21 22 Q. Did I highlight that? I gave you the wrong 22 conference case, okay. 23 23 copy, I'm sorry. Can I get that back? Then, for this case, we have three 24 A. That's okay. specimens, right, A, B, and C. Only C is the mesh 25 MR. THORNBURGH: I'll re-mark it. specimen. A and B -- between the B specimen -- in the B Page 91 Page 93 MR. VOUDOURIS: For the record, this 1 specimen, you have a urothelial papilloma, which is 1 2 considered as a small benign tumor, okay? Then, for 2 document says case conference -- consensus conference 3 some -case, but it doesn't reflect which specimen, A, B, or C, was part of the consensus conference case. Q. (BY MR. THORNBURGH) That's -- strike that --5 MR. THORNBURGH: I appreciate the speaking 5 well, excuse me. I don't mean to interrupt, but small 6 objection. benign tumor, is that what you said, papilloma? 7 MR. VOUDOURIS: Does this exhibit have any A. Yes, uh-huh. highlighting of yours in it? 8 Q. That's nothing serious, right? 9 9 MR. VOUDOURIS: Objection. MR. THORNBURGH: That does not. 10 Q. (BY MR. THORNBURGH) So my question is, you 10 Q. (BY MR. THORNBURGH) Nothing significant? 11 see on page Bates number ending in -08 of Exhibit 11 MR. VOUDOURIS: Objection. 12 Number 6 under the file -- final diagnosis, it says 12 A. Well, if it is true, it's nothing serious. 13 consensus conference case? However, if for some inexperienced pathologist, or the 14 A. Which sentence says that? pathologist who does not have much experience about this 15 Q. Under -- under final diagnosis C, eroded diagnosis, then they will show in the consensus meeting, and then try to get confirmation of the diagnosis. 16 vagina mesh. 17 MR. VOUDOURIS: Objection. That's usually the case. If you want to confirm whether 18 this is correct, then you can call the pathologist, what A. The gross description or microscopic -- okay. 19 Consensus conference case, okay. All right. 19 does it mean, and they will explain to you in detail. MR. VOUDOURIS: There's no question. He Q. (BY MR. THORNBURGH) Okay. So let me ask you 20 20 just asked you if you saw it. this: In a consensus conference case, does the 21 pathology -- final pathology report get issued before or 22 A. I see it, but can I explain to you? 23 MR. VOUDOURIS: Hold on. He just asked 23 after the conference?

24

25

25 question.

24 you a question and you answered it. Wait for the

MR. VOUDOURIS: Objection; form --

A. Because pathology report --

Page 94 Page 96 1 MR. VOUDOURIS: -- and foundation. 1 associated with foreign body giant cell reaction and 2 A. Pathology report almost always released after chronic inflammation, right? 3 consensus meeting. 3 A. Yes. That's always the case. Q. (BY MR. THORNBURGH) So is it your 4 Q. It doesn't say mild, right? 5 understanding, based on your review of the pathology 5 MR. VOUDOURIS: Objection. 6 report, that this pathology report most likely was A. You can read. It does not -- it's not there. 6 submitted after the consensus conference took place? People -- if that's why --8 MR. VOUDOURIS: Objection; form, MR. VOUDOURIS: You've answered his 9 foundation. question. Q. (BY MR. THORNBURGH) It doesn't say mild 10 A. Yes, this is usual case. 10 11 Q. (BY MR. THORNBURGH) And according to the 11 inflammatory response, right? 12 pathologist -- or the pathology report, which is marked 12 A. Based on this report. 13 13 as Exhibit Number -- within -- contained within Exhibit MR. THORNBURGH: I've got to take a bio 14 Number 6 and found on the -- the final diagnosis found 14 break. 15 on 00009, "The consensus was skin and fibroadipose THE VIDEOGRAPHER: We're off record at 16 tissue with mesh and associated foreign body giant cell 16 11:39 a.m. 17 reaction and chronic inflammation" [as read]? (Break taken.) THE VIDEOGRAPHER: We're back on record at 18 MR. VOUDOURIS: Objection; form and 18 19 19 12:43 p.m. foundation. 20 20 Q. (BY MR. THORNBURGH) Doctor, did you have a A. The consensus conference case in the last line 21 for this report does not specifically indicate this is 21 good lunch? 22 for specimen C, okay? It is just only indicated this 22 A. Yes. Thank you. 23 case, all right, somehow has been just gone through the O. Okay. Good. consensus meeting. That's my understanding. 24 Doctor, I just want to circle back to a 25 It certainly does not indicate the mesh couple of things that you testified to before we went on Page 95 Page 97 1 is -- just goes through the consensus meeting. Because 1 our lunch break. One of the things you'd indicated --2 I can guarantee, all right, in United States not -- I 2 I'm not going to go into great detail and re-ask these 3 can say majority of the pathologists is not going to 3 questions, but one of the things you indicated was that 4 show the mesh around to say, okay, do you recognize this 4 you were developing -- or wanted to develop a protocol 5 as mesh material? No. There's no meaning for a 5 or to find a protocol in the publication that you're 6 pathologist usually, right? They just describe what planning to publish? 7 they --A. Yes. 8 MR. VOUDOURIS: You've answered his Q. Okay. And does that include a protocol for 9 question. grading your pathological findings? 10 Q. (BY MR. THORNBURGH) The -- the -- you would 1.0 MR. VOUDOURIS: Objection. 11 agree with me that, in any event, number one, under the 11 Go ahead. eroded and vaginal -- eroded vaginal mesh, final 12 A. I think we are planning to generalize those diagnosis, it says consensus conference case, right? guideline for all -- for majority of the surgical 14 MR. VOUDOURIS: Objection -pathologists to -- who is going to encounter or receive 15 Q. (BY MR. THORNBURGH) That's what it says? these specimens, how to handle them, number one, grossly 16 MR. VOUDOURIS: Objection; form, and microscopically. 16 17 17 foundation. And microscopically, yes, we will Q. (BY MR. THORNBURGH) That's where it appears 18 illustrate what are the most common findings they should 19 on the pathology report, right? describe, such as -- include -- data will include

25 Mrs. Corbet's explant indicates that the mesh was

23 and chronic -- and -- and inflammatory response

24 identified on this pathologist -- pathology report from

A. It -- it's on the pathology report, it's

Q. And the conclusion regarding the foreign body

20

22

21 obvious.

information -- amount of information or the degree of

protocol include grading the degree of, for example,

A. Yes. We are going to put mild -- no

Q. (BY MR. THORNBURGH) And does part of that

information, that's true.

inflammation on some sort of scale?

22

24

- 1 information will be 0, mild will be 1, moderate will be
- 2 2, then severe or marked will be 3. Those are typical
- 3 grading system being used in the general surgical
- 4 pathology practice.
- 5 Q. And within each one of those subgrades, do
- 6 you -- are you -- do you plan on providing some type of
- 7 guideline based on your -- or the morphological findings
- 8 under the slide, for example, if you see a certain
- 9 amount of neutrophils, you get a certain grade, or if
- 10 you see a certain amount of giant cells, you get a
- 11 certain grade for -- is that how it works?
- 12 A. Yes. I think this is -- will be very much
- 13 similar to Hill's paper I already described.
- Q. Have you already created or drafted the
- 15 protocol?
- MR. VOUDOURIS: Objection.
- 17 A. No.
- MR. VOUDOURIS: Asked and answered.
- 19 Q. (BY MR. THORNBURGH) Did you -- did you -- so
- 20 you didn't use that type of grading system in your
- 21 evaluation of Mrs. Corbet's explant material, correct?
- 22 MR. VOUDOURIS: Objection.
- A. In -- for Mrs. Corbet's case, I have described
- 24 based on my findings, yes. I used a grading system.
- Q. (BY MR. THORNBURGH) Is the reason why you --

- Page 100
 - inflammatory cell or not inflammatory cell, then we will
 turn on a high power to confirm.
 - Q. So at first, you start with a 4X power?
 - 4 A. Typically.
 - 5 Q. And you scan the entire specimen?
 - A. Correct.
 - Q. And -- and look for the morphological features
 - 8 of the specimen?
 - 9 A. Correct.
 - Q. Like the number of inflammatory cells?
 - 11 A. Correct.
 - Q. Like the number of foreign body giant cells?
 - 13 A. Correct.
 - Q. Or multinucleated giant cells?
 - A. Giant cells, that means multinuclear giant
 - 16 cells.
 - Q. And the purpose of that is to create an
 - 18 objective way to grade rather than a subjective
 - 19 analysis?
 - 20 A. Correct. And if in the long-term run, if many
 - 21 such findings accumulate, then these data can be
 - 22 analyzed together.
 - Q. And you -- I think you said that your -- the
 - 4 criteria is essentially based on the guidelines
 - discussed in the Hill article, right?

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1

- 1 you're developing this protocol, want to publish this
- 2 protocol, to provide objective criteria so that the
- 3 pathological findings are less subjective?
- 4 A. Correct.
- 5 Q. So the grading, for example, for inflammation
- 6 or the inflammatory response based -- based on the
- 7 number of inflammatory cells that are present in a
- 8 microscopic slide?
- 9 MR. VOUDOURIS: Objection.
- 10 A. Yes. Based on the number, then the -- the
- 11 extensiveness and the locations -- close -- the
- 12 relationship with the mesh fiber spaces.
- Q. (BY MR. THORNBURGH) And how do you determine
- 14 the extensiveness of the inflammatory response? Is that
- 15 also based on the number of inflammatory cells present
- 16 in the slide?
- 17 A. Usually we will enter lower power, for
- 18 instance, 4X, and then we will see how many foci of
- 19 these inflammations will be localized within the slide.
- 20 That's so-called extensiveness.
- Q. So you'll see the -- you'll use 4X, and that's
- 22 the magnification?
- A. That's usually -- 4X, sometimes, yes. In a --
- 24 in a scanning situation, you use -- we use lower power.
- 25 Then, if -- when we want to confirm these are

- MR. VOUDOURIS: Objection.
- 2 A. It's not based on, because this is a
- 3 general -- in general practice, within the pathology,
- 4 people use these criteria to describe. That's so-called
- 5 semiquantitative method. It's not exact quantitative.
- 6 Semiquantitative method.
- 7 Q. (BY MR. THORNBURGH) And so I'm just trying to

- 8 understand. Are you saying that the authors -- that
- 9 the -- that the people that published -- the doctors
- 10 that published the Hill article called histopathology of
- 11 excised midurethral -- urethral sling mesh use a
- 12 semiquantitative method?
- MR. VOUDOURIS: Objection.
- 14 A. Yes.
- Q. (BY MR. THORNBURGH) And in your guidelines
- that you want to publish, how would you define mild
- 17 inflammation?
- 18 MR. VOUDOURIS: Objection. Counselor, we
- 19 talked about his protocol this morning. We've already
- 20 discussed that your deposition today is Corbet fact
- 21 specific. You have gone far afield of that. I've given
- 22 you a leeway.
- 23 MR. THORNBURGH: I'm -- I'm not trying to.
- MR. VOUDOURIS: But you have. And -- and
- 25 let's stop and let's move on, and let's ask about fact

Page 102 Page 104 1 specific Corbet topics. 1 If there is basically no easily 2 MR. THORNBURGH: Well, I'm tying this all 2 identifiable inflammatory cells, then we will classify it as no information. And if we see clusters of these 3 into the fact specific. My -- my question is absolutely related to Corbet. inflammations relatively easily identifiable surrounding 5 MR. VOUDOURIS: How so? the mesh fiber spaces, then we will say that's moderate, 6 all right, in addition to some of these giant cells. MR. THORNBURGH: Because I want to know -because you're going to find out, but I want to -- I Then, if we see huge amount of accumulation of want to know -inflammatory cells, all right, in large amount of area, 9 Q. (BY MR. THORNBURGH) Let me ask you this then we say that's a severe or marked. That's so-called 10 question: You didn't use -- is it fair to say that you a semiquantitative grading system. 11 did not use the criteria that was identified -- or the 11 Q. (BY MR. THORNBURGH) Okay. And so I'm just 12 guidelines -- grading guidelines that were used in the 12 trying to understand how you applied it to Mrs. Corbet's 13 Hill article in your evaluation of Mrs. Corbet's case. When you say "sparse," what does that mean 14 pathology slides? specifically? 15 MR. VOUDOURIS: Objection, compound. 15 A. Shall I show you pictures I have? 16 A. Hill article published it this year, right? 16 Q. No. I'm just -- I'm just talking --17 A. Right. Then within the picture, then you can 17 And that's why I say the grading system -- or semiquantitative grading system for the amount of see much better. Otherwise, we are talking -- when I inflammation is generally accepted within the pathology describe I have picture in my mind, but you are not 20 field. That's the criteria I'm using, and also many pathologist, you don't understand what I'm talking, so other pathologists are using if they want to use -- to we are making circles. So the best thing is pointing grade the amount of inflammation. with a picture, I can show you what -- exactly what I 22 23 O. (BY MR. THORNBURGH) Okay. So is that the 23 mean. criteria that you used in your evaluation of 24 Q. We're about ready to go through -- we're going 25 Mrs. Corbet's pathology? to go through your entire report, case specific Page 105 Page 103 A. Correct. 1 1 report --2 MR. THORNBURGH: That's why I'm trying --2 A. Okay. Q. -- here in a moment. 3 that's why I'm asking these questions. Q. (BY MR. THORNBURGH) And so how -- using that But is it fair to say that -- that -- that 5 criteria, how many inflammatory cells identified in an individual pathologist's definition of sparse -- or 6 the -- a single mesh specimen would lead you to conclude 6 observation of sparse inflammatory cells is still 7 that the inflammatory response was mild? subjective, or is there a -- is there -- are there 8 MR. VOUDOURIS: Objection, again, that is objective criteria that lead to a conclusion that the 9 not case specific to Corbet. inflammatory response -- inflammatory cells are sparse? 10 MR. THORNBURGH: He said -- he said that 10 MR. VOUDOURIS: Objection. he used this in the Corbet case, so I'm trying to figure 11 A. There is variation, that's for sure. Because 12 it out. I don't know how that's not specific to Corbet. a semiguantitative method, all microscopic observation, there is certain degree of variation. That's for sure, 13 THE WITNESS: Should I answer? 14 MR. VOUDOURIS: Go ahead. okay. But more or less, in general, people agree on. 15 THE WITNESS: That's not a big issue. 15 Q. (BY MR. THORNBURGH) Are -- is there a 16 A. Mainly, as I said, this is -- first of all, 16 different method than semiquantitative? 17 17 this is semiquantitative method, okay? The amount of A. There is no definitive method except some inflammation or the degree of inflammation is not based people like to use, like, immunohistochemical stainings. on pure number of the inflammatory cells, all right? For instance, like a CD68 can identify the number of That's so-called semiquantitative. 20 20 inflammatory cells. We see amount of in -- inflammation 21 But still even though they use 22 surrounding certain area. If they sparse, only few, immunohistochemical stainings, then overall is not going 23 small amount in the lower power, then confirm in the to count the individual cells, how many cells, give you 24 higher power, then that's considered as a mild or even a specific number. Still give you ballpark, roughly, 25 minimal. Minimal, mild is basically the same, okay? amount how much is mild or is moderate or severe.

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- 1 That's the situation.
- 2 Q. I think I understand.
- 3 A. Right.
- 4 Q. The other thing I wanted to circle back around
- 5 on was, you said that you recently left your employment
- 6 with the University of Arizona?
- A. Correct.
- 8 Q. What was the reason for leaving University of
- 9 Arizona?
- 10 MR. VOUDOURIS: Objection.
- 11 Go ahead.
- 12 A. UT Southwestern provides a better opportunity
- 13 for my academic practice.
- Q. (BY MR. THORNBURGH) Okay. So you're -- when
- 15 did you leave University of Arizona?
- 16 A. That was July of this -- this year.
- Q. Okay. And you accepted a position at UT
- 18 Southwestern in July of this year as well?
- 19 A. Yeah. That's the --
- 20 Q. That's why --
- 21 A. Right.
- 22 Q. And what position did you accept at UT
- 23 Southwestern? What's your current position there?
- 24 A. I'm a tenured full professor of pathology as
- 25 well as obstetrics and gynecology. And then also, I

- Page 108

 1 you know, what exactly the clinical manifestation should
- 2 be -- or would be -- in this particular case.
- Q. (BY MR. THORNBURGH) You said most of the
- 4 time. Are there -- is there any -- has there ever been
- 5 a time that you have correlated your histopathological
- 6 observations of an explanted mesh to the clinical
- 7 findings discussed in medical records?
- 8 A. Oh, yes.
 - MR. VOUDOURIS: Objection.
- 10 A. Yes. In the past, for instance, if I found
- 11 marked amount of inflammation, including pus formation
- within the specimen, then that's correlated to the
- 13 clinical finding of infection. You know, those are
- 14 situation.
- 15 Q. (BY MR. THORNBURGH) Since your last
- 16 deposition -- I believe I read in one of your
- 17 depositions that you're receiving one or two explant
- 18 meshes per week for a period of time? I'm just trying
- 19 to understand. Has that changed since your last
- 20 deposition?
- A. Still similar, when I was in Arizona.
- Q. So when you were in Arizona up until the time
- 23 you left, you were receiving on a weekly basis one to
- 24 two mesh explants?
- MR. VOUDOURIS: Objection.

- 1 have endowed distinguished professorship in UT
- ² Southwestern. Then I'm also the group leader as the
- 3 chief of the GYN pathology group. Within this group, I
- 4 have 10 pathologists involved.
- Q. Now, in preparing to offer opinions in this
- 6 case, what were you asked -- case specific, what were
- ⁷ you asked to do -- what was -- strike that.
- 8 What did you do to come to your
- 9 opinions -- case specific opinions in Mrs. Corbet's
- 10 case? What did you review?
- 11 A. I reviewed the slides, reviewed the medical
- 12 records, reviewed some depositions from surgeons, and
- 13 then generated my idea -- or my opinion.
- 14 Q. Okay. So you reviewed the medical records,
- 15 you reviewed the pathology material, and you reviewed
- 16 depositions?
- A. Right. And also including plaintiff's expert
- 18 report, because I have to address those specific points.
- Q. And did you attempt to correlate the clinical
- 20 findings identified in the medical records to your
- 21 pathological findings?
- MR. VOUDOURIS: Objection.
- Go ahead.
- A. I tried, but from histological point of view,
- 25 all the histological findings usually do not predict,

- Page 109
- A. You mean -- you mean UT Southwestern or --
- Q. (BY MR. THORNBURGH) Sorry. So -- you left
- 3 Arizona in 2000 --
 - A. Yes.
- 5 Q. -- July of 2015?
- 6 A. Right.
- 7 Q. I think your last deposition was in --
- 8 MR. VOUDOURIS: April.
- 9 Q. (BY MR. THORNBURGH) -- 2000 -- April 2014.
- 10 So was it consistent during that time period that you
- 11 would continue to receive one to two explants --
- 12 A. Yeah.

- Q. -- explant -- mesh explants per week?
- 14 A. Correct.
- Q. And since April of 2014, have you received TVT
- 16 mesh explants at your facility?
- A. I can't be sure, because typically, in the
- pathology requisition sheet, they do not specify this is
- 19 TVT versus any other types of sling. But they do
- 20 indicate this is a mesh -- vaginal mesh specimen.
- Q. Are there any -- have you -- in your
- 22 experience, have you identified any morphological
- 23 features of a mesh that could allow you to assume or
- 24 conclude that the mesh explant was a TVT?
- MR. VOUDOURIS: Objection. This line of

Case 2:12-md-02327 Document 2834-4 Filed 09/19/16 Page 30 of 73 PageID #: 98307 Wenxin Zheng, M.D. Page 112 Page 110 1 questioning --2 MR. THORNBURGH: I -- I -- yeah. 2 explanted, correct? 3 MR. VOUDOURIS: -- was already asked in A. Correct.

6 trying --Q. (BY MR. THORNBURGH) I mean, for the -- for

MR. THORNBURGH: Okay. I -- I'm just

8 the --

9 MR. VOUDOURIS: It already has.

Q. (BY MR. THORNBURGH) For the mesh that you've 10

11 looked at in the last year that you've received on a

12 weekly basis, did any of those contain blue fibers?

13 A. Oh, yeah. We -- many of such specimens have

14 blue plastic piece.

4 his prior deposition.

5

15 Q. By "blue plastic piece," you mean the blue

16 fiber?

17 A. Blue mesh filament.

Q. Since April of 2014, how many mesh explants 18

19 have you received that have blue mesh filaments?

A. I don't know the answer because I didn't 20

21 calculate.

22 Q. Majority?

23 MR. VOUDOURIS: Objection.

A. As I said, probably it's not a good idea to

25 give you just estimation since I do not really count --

Q. And in 2013, she had a mesh -- her mesh was

Q. And what was your understanding based on your

5 review of the medical records and your reading of

6 Dr. Smith's deposition, who explanted the mesh, what

7 was -- what were -- what were the reasons why -- or the

reasons for Mrs. Corbet undergoing the mesh explant?

MR. VOUDOURIS: Objection; compound.

10 Q. (BY MR. THORNBURGH) I'll ask a better 11 question.

12 Based on your review of the medical

records and Dr. Smith's testimony, what is your

understanding for the reason for Mrs. Corbet having her

TVT mesh explanted?

16 A. Because Dr. Smith found an area of mesh

exposure.

18 Q. You did read the medical records and you did

read Dr. Smith's testimony, right?

20 A. Right.

21

Q. She -- she testified there was more than that

22 reason for the removal of the mesh ex -- of the TVT

mesh. correct?

24 A. I think this is the main reason because

exposure. Then patient also complained of pain. And

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1 you know, calculate how many exactly we have for those

2 specimen contains blue mesh.

Q. (BY MR. THORNBURGH) And based on your

4 review -- so let's talk about the medical --

5 Mrs. Corbet's medical records --

6 A. Sure.

7

O. -- a little bit --

8 A. Sure.

9 Q. -- her medical history. Based on your review

10 of Ms. Corbet's medical records, did you come to

11 understand that she had a TVT mesh implanted in 2011 to

12 treat stress urinary incontinence?

13 A. Yes.

Q. And did you -- also based on your review of

15 her medical records, did you -- did you know -- did you

16 come to understand that she had the TVT mesh explanted?

17 A. A year later. And before -- in the surgery,

18 she also -- because she had prolapse, like cystocele and

19 rectocele, and the prolapse repair surgery was done too

20 at the same time.

Q. Yeah. So that was -- so during her implant

22 procedure, she had a anterior colporrhaphy and a

posterior colporrhaphy, right?

24 A. Posterior colporrhapy, right, uh-huh.

25 Correct.

Page 113 1 then, you know, that was -- the common reason, if any

2 doctor finding mesh exposure, this could be the

3 indication to remove.

Because if you leave exposed the mesh in

5 the body, then that will cause more, like, complications

6 such as infection. Because vagina is environment

7 exposed to outside and is -- is not, like, aseptic

condition. So, basically, has a more chance to expose

to bacteria as a contact. So that's the reason.

Q. Do you under -- I'm going to just see if I

understand. Was it your understanding from reading the

12 medical records and -- and Dr. Smith's testimony that

the mesh was explanted as a result of both the mesh

exposure and the -- her pain that she was experiencing?

A. I think that's the reason Dr. Smith explanted 16 the part of the mesh.

17 Q. And did Dr. Smith also testify that another

reason she explanted the mesh was because of the voiding

dysfunction that Mrs. Corbet was experiencing after the

20 mesh implant?

22

21 A. I was not aware of this.

Q. Based on your review of the medical records,

23 did you come to understand that after Mrs. Corbet was

24 implanted with the TVT device, at some point in time

after the implant, she experienced void -- voiding

Page	1	1	4
I age	1	1	

- 1 dysfunction?
- 2 A. I think so, yes. Probably was true, but I did
- 3 not pay that attention.
- 4 Q. Did you come to understand that after the mesh
- 5 was implanted that Mrs. Way [sic] began to experience
- 6 overactive bladder?
- 7 A. Yes. That's in the medical record, Dr. Smith
- 8 did mention that. I -- that one, I remember that.
- 9 Q. Is it your understanding that overactive
- 10 bladder and urge incontinence is the same thing?
- 11 MR. VOUDOURIS: Objection.
- A. Not in my specialty. Overreaction probably
- 13 somehow has some kind of urgency, more frequency for --
- 14 for voiding issue.
- Q. (BY MR. THORNBURGH) You said overreaction?
- 16 A. Overreactive bladder syndrome, basically,
- 17 right, you are talking about?
- Q. No, not overreaction. I want to talk about
- 19 overactive bladder disorder.
- 20 MR. VOUDOURIS: Objection.
- A. Overreactive bladder is a clinical term. I'm
- 22 not -- usually belong to urology, okay? It's not belong
- 23 to obstetrics and gynecology, so I'm not expert for that
- 24 part.
- Q. (BY MR. THORNBURGH) My only question is:

- Page 116
- the jury and the ladies and gentlemen -- and the court,
 you did not perform a pelvic examination of Mrs. Corbet,
- 3 correct?
- A. Correct.
- Q. Is it fair to say that you would defer to
- 6 physicians who have performed a pelvic examination
- 7 concerning their differential diagnosis of Mrs. Corbet?
- 8 MR. VOUDOURIS: Objection.
- A. That's not my -- my expert field, because I'm
- 10 a pathologist. I provided pathological finding, you
- 11 know, opinion regarding what I have observed under the
- 2 microscope.

13

- Q. (BY MR. THORNBURGH) So is it fair to say
- 14 that -- let me strike that.
 - You saw in Dr. Smith's testimony she
- testified that the cause of Mrs. Corbet's erosion and
- 17 dyspareunia was the mesh. You saw that, right?
- 18 MR. VOUDOURIS: Objection.
- 19 A. I didn't see that.
- 20 Q. (BY MR. THORNBURGH) You didn't -- did you
- read the depo transcript -- the deposition transcript of
- 22 Dr. Smith?
- A. I -- I read the depo, but I did not see that
- 24 kind of sentence saying Dr. Smith says dyspareunia is
- 25 caused by mesh. However --

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- 1 When you reviewed the medical records of -- of
- 2 Mrs. Corbet, did you see from your review of those
- 3 records that after the TVT device was implanted, that
- 4 Mrs. Corbet was diagnosed with overactive bladder
- 5 disorder?
- 6 MR. VOUDOURIS: Objection.
- 7 A. I noticed that this has been stated in the
- 8 report.
- 9 Q. (BY MR. THORNBURGH) You don't have an opinion
- 10 one way or the other, I assume, that whether or not the
- 11 mesh caused overactive bladder?
- 12 MR. VOUDOURIS: Objection.
- A. I don't have any opinion about this because
- 14 that's outside of my expertise.
- Q. (BY MR. THORNBURGH) So is it fair to say that
- 16 you're not going to come and testify at trial and offer
- 17 an opinion that Mrs. Corbet's overactive bladder
- 18 dysfunction was or wasn't caused by the mesh?
- MR. VOUDOURIS: Objection; asked and answered.
- 21 A. I think that's -- that -- yes, I'm not going
- 22 to provide my opinion related -- regarding the
- 23 relationship between the mesh implantation and bladder
- 24 overreaction.
- Q. (BY MR. THORNBURGH) And just for purposes of

- MR. VOUDOURIS: Hold on. You answered his
- 2 question.
- Q. (BY MR. THORNBURGH) Dr. Smith is the medical
- 4 doctor who was actually treating Mrs. Corbet's medical
- 5 condition after mesh implantation, correct?
- 6 A. Yes.
- 7 Q. And you -- you are not going to criticize
- 8 Dr. Smith's observations of Mrs. Corbet during her care
- 9 and treatment of the plaintiff, correct?
- 10 A. There is no reason for me to criticize the
- 11 commission's finding or description.
- 12 And -- but I think I want to clarify two
- 13 things. One is if somebody or a patient who has mesh
- 14 exposure, then exposed mesh may cause pain. That's
- 15 reasonable. But if this -- any patient if complains of
- 16 pain and then when they receive mesh implantation,
- 17 there's no such relationship. Says anyone
- 18 receive the -- because of the patient receiving -- or
- 19 received mesh implantation, then she also complains of
- 20 pain, then the pain is caused by mesh. That's two
- 21 different issues. You understand what I'm talking?
- So my understanding at the beginning, you
- were asking me if Dr. Smith made a statement, says
- 24 Mrs. Corbet, the pain complain is caused by mesh.
- That's why I -- I say I did not see that. But if you

Page 1	18
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- 1 are saying -- if -- but I do remember Dr. Smith already
- 2 stated she -- clinically she found mesh exposed area --
- 3 or mesh exposure -- in the focal area of the vagina.
- 4 That's the statement.
- 5 Q. Do you -- and then do you recall that she also
- 6 testified that the mesh exposure caused Mrs. Corbet's
- dyspareunia or painful intercourse?
- MR. VOUDOURIS: Objection.
- A. I don't remember says this is the exact cause, 9
- 10 the only cause for -- for her pain. But based on my
- 11 understanding, yes, anything exposed, mesh, may be
- 12 related to the pain, or it's uncomfortable feeling.
- 13 That's a common sense.
- Q. (BY MR. THORNBURGH) You -- and you're not 14
- 15 going to come in and testify that Mrs. Way's [sic]
- dyspareunia wasn't caused from the mesh exposure; is
- that right?
- 18 MR. VOUDOURIS: Hold on. Objection. I
- 19 think you keep saying Mrs. Way's.
- 20 MR. THORNBURGH: I'm sorry, Mrs. Corbet.
- 21 I have a trial...
- Q. (BY MR. THORNBURGH) For Mrs. Corbet, when you 22
- 23 come and testify at trial, is it fair to say that you're
- 24 not going to testify or offer opinions that her
- dyspareunia was not caused from her mesh exposure?

- Page 120 Q. And what would a mesh erosion or exposure look
 - 2 like microscopically? What would -- what would be the
 - features?
 - A. Classic feature for exposure or erosion is
 - squamous mucosa on the top but disrupted, number one.
 - Then just right underneath of this disruption area, we
 - will see the mesh fiber just immediately underneath or
 - just exposed in the disrupted area. Then -- and then
 - usual -- typically, this area will be associated with
 - more intense inflammation. That's the histological
 - finding for mesh exposure or erosion.
 - Q. Similar question: What would be the
 - pathological features of a mesh that was contributing to
 - 14 pain?

15

- MR. VOUDOURIS: Objection. All of these
- areas of questioning were asked during his prior
- deposition, so, again, we're plowing the same field
- 18 again.
- 19 MR. THORNBURGH: Well, I'm just trying to
- 20 find out if any of those -- you know.
- MR. VOUDOURIS: Dan, with all due
- 22 respect --
- 23 MR. THORNBURGH: I -- I -- I'm not
- 24 trying -- I'm not trying to plow the same field, so I'm
- 25 not -- that's not --

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- MR. VOUDOURIS: Objection; form. 1
- A. I think I'm going to provide my opinion based 2
- 3 on the pathological findings I have found. Then there
- 4 is no histological evidence for me to say, all right,
- 5 this is the -- her dyspareunia complaining is caused by
- 6 the histological finding I have observed. Is that
- 7 clear?
- 8 Q. (BY MR. THORNBURGH) So let me just make sure
- 9 I understand your opinions. If Dr. Smith, Mrs. Corbet's
- 10 treating physician, testified that the mesh exposure was
- 11 causing Mrs. Corbet's painful intercourse, are you going
- 12 to suggest or opine at the -- at the trial that
- 13 Dr. Smith was wrong?
- A. That's totally different question.
- 15 Dr. Smith's finding is a clinical finding. And my
- 16 finding is a pathological finding. So my opinion will
- be based on the pathological finding, and I -- I'm not
- 18 in the position to comment Dr. Smith's finding or
- 19 statement is wrong or is correct.
- 20 Q. Did you find path -- did your -- strike that.
- In your pathological evaluation of
- 22 Mrs. Corbet's explant, did you identify evidence of mesh
- 23 erosion?
- 24 A. I tried very hard, but I don't see a good
- 25 evidence of mesh exposure or erosive site.

MR. VOUDOURIS: That field has been

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2 plowed.

1

- 3 MR. THORNBURGH: All right, let's do this.
- (Exhibit Number 7 was marked.)
- O. (BY MR. THORNBURGH) I'll mark as Exhibit
- 6 Number 7 the medical records from North Dover OB/GYN
- Associates. Did you review the records from North Dover
- OB/GYN Associates in preparation for your expert report?
- 9 A. I briefly went through that, because there's
- 10 not really many pathological related things here. Yes.
- Q. If you'll turn to -- in Exhibit Number 7, if 11
- 12 you'll turn to Bates number ending in -23.
- 13 A. Yes.
- Q. And you see this record is electronically
- 15 signed -- turn the page to 24.
- 16 A. This one [indicating], right?
- 17 Q. Yes. If you'll turn the page, you'll see that
- 18 it was electronically signed by Dr. Russell Harrell?
- 19 A. Uh-huh, yes.

- 20 Q. And you understand that Dr. Russell Harrell --
- 21 A. Who was the surgeon implanted the mesh.
- 22 Q. Okay. And so based on this record, what were
- the clinical symptoms that Mrs. Corbet was experiencing 23 at the time that she saw Dr. Harrell on March 23, 2011?
- A. She had grade 1 cystocele, grade 2 rectocele 25

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1 we mentioned previously.

2 Q. Okay. And if you look to the social

- 3 history --
- 4 A. Social history?
- 5 Q. Yeah. Do you see that there on Bates number
- 6 -23?
- A. Alcohol use, drinks occasionally; and tobacco
- 8 use, denies; then recreational drugs, denies; then diet,
- 9 balanced diet; lifestyle, active lifestyle.
- Q. Okay. So based on this record, which is --
- 11 which was recorded prior to her implant procedure, would
- 12 you agree that -- that Ms. Corbet was not a smoker?
- 13 A. Looks like it.
- MR. VOUDOURIS: According to the record.
- 15 A. According to the record.
- Q. (BY MR. THORNBURGH) Not a smoker?
- 17 A. Yeah. According to the record, yeah.
- Q. Did you see any evidence in any of the medical
- 19 records that she was a smoker?
- 20 A. No.
- Q. Okay. And she only occasionally drank
- 22 alcohol, right?
- A. Based on the record.
- Q. And so smoking was not a risk factor for
- 25 Mrs. Corbet with respect to erosion, based on your

- 1 complications, right?
 - 2 A. Correct.
 - 3 Q. And Mrs. Corbet was not a smoker, didn't have
 - 4 diabetes, and wasn't obese, correct?
 - 5 MR. VOUDOURIS: Objection.
 - A. What else I mention in the risk factor
 - 7 category?
 - 8 O. (BY MR. THORNBURGH) Well, what are the other

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- 9 risk factors?
- A. Right. So you -- I think you are
- 11 intentionally ignore. And, also, I said lower estrogen
- 12 level, okay? Lower estrogen level. Lower estrogen
- 13 level actually is the main factor.
- Q. So what's the basis for your opinion that
- 5 because, number one, that Mrs. Corbet had a lower
- 16 estrogen level?
- A. She's a postmenopausal, right, 61 years old.
- Q. So postmenopausal, 61 years old?
- 19 A. Right.
- Q. Any other basis?
- 21 A. That's classical situation for a lower
- 22 estrogen level.
- Q. And so what -- are you referring -- is there
- 24 some publication that says that if you have lower
- 25 estrogen levels, you're at risk of suffering some

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- 1 review of the medical records, correct?
- 2 MR. VOUDOURIS: Objection.
- A. You are talking about individual patient, then
- 4 try to generalize the conclusion. So I think it's
- 5 irrelevant.
- 6 Q. (BY MR. THORNBURGH) Well, you've offered
- 7 opinions that some of the risk factors that lead to
- 8 mesh-related complications would be things like diabetes
- 9 and smoking, right?
- 10 A. Yes. Based on literature, it says in that
- 11 way, that's true.
- Q. So my only question is, because Mrs. Corbet
- 13 was not a smoker, that wasn't a risk factor for a
- 14 mesh-related complication, right?
- A. But if she has other risk factors, it's --
- 16 that's why it's individually based. It's not because
- 17 she has -- she's not smoker, then she has no risk
- 18 factor.
- Q. We're going to talk about all those, but in
- 20 your report, you'd indicated there were certain risk
- 21 factors that individual patients had, and you indicated
- 22 that smoking was a risk factor, diabetes was a risk
- 23 factor, and obesity --
- 24 A. Correct.
- 25 Q. -- were risk factors for mesh-related

- 1 mesh-related complication?
- 2 A. Because lower estrogen level -- women with
- 3 lower estrogen level are postmenopausal situation. The
- 4 vagina tend to become atrophic; therefore, atrophic
- 5 one -- vaginas will have a thinner mucosa lining. And
- 6 the thinner mucosa linings has a tendency to have injury
- $^{7}\,\,$ or dyspareunia, or even if you have an implantation of
- 8 the mesh, then it's -- it's being considered as a risk
- ⁹ for mesh exposure.
- Q. If you look at page -- the report that starts
- 11 on page 23, is there any indication in this report at
- 12 this time that Mrs. Corbet had vaginal atrophy?
 - A. It's not stated.

- Q. Based on your review of the medical records,
- when was Mrs. Corbet first diagnosed or -- or observed
- to have vaginal atrophy?
- 17 A. Vaginal atrophy diagnosis usually is not being
- provided, okay, because this is a common situation in
- 19 postmenopausal women.
- Q. What level of vaginal atrophy places a patient
- 21 with a mesh device at risk of developing a mesh-related
- complication?MR. VOUDOUR
 - MR. VOUDOURIS: Objection.
- A. I'm not able to -- to provide accurate number
- 25 of, you know, what the level -- what the percentage of

- 1 the risk the lower estrogen may contribute, but overall,
- 2 this is accepted concept in the field. Postmenopausal
- 3 woman has a tendency to complain this, okay?
- 4 Q. (BY MR. THORNBURGH) And you -- do you
- 5 understand from looking at the medical records that
- 6 Mrs. Corbet was taking hormone replacement therapy?
- A. I was not aware how long she was taking the
- 8 hormone replacement, number one.
- 9 Number two, I also notice that there's a
- 10 pathology report from -- I think from the report that we
- 11 just discussed before lunch. In the microscopic
- 12 discussion description, it says there is fibrosis in the
- 13 vaginal mucosa they trimmed, okay? So that is the part
- 14 of the evidence -- pathological evidence to support
- 15 the -- the vagina has at least certain degree of
- 16 atrophy.
- Q. Fine. So it's your --
- 18 A. Fibrosis.
- Q. It's your testimony that based on one of
- 20 Mrs. Corbet's -- in fact, the explant pathology report
- 21 from the procedure that removed the TVT, the finding of
- 22 fibrosis in the vaginal mucosa was evidence of atrophy?
- MR. VOUDOURIS: Objection to form.
- 24 A. No. No.
- Q. (BY MR. THORNBURGH) I thought -- I'm just

- Q. What part of the vagina?
- 2 A. I think you -- if you want to know exact --

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- Q. Go to page -- go to page -49. We'll look at
- 4 the implant operative report.
- 5 A. Yeah.

1

12

15

- 6 Q. Okay. You see that this is -- the date of the
- ⁷ surgery was July 14th, 2011?
- 8 A. Right. The same date for the implantation.
- 9 Q. Okay. And the procedure was an anterior and
- 10 posterior repair of -- colporrhaphy?
- 11 A. Right.
 - Q. And for the benefit of the jury and the court,
- what is a colporrhaphy?
- A. It's a repair of the prolapse, basically.
 - Q. Using what?
- A. Using -- I'm not -- because I'm not a surgeon,
- 17 okay? I don't know what kind of material they use or
- 18 they -- what kind of method to use. Mainly -- the main
- 19 purpose for this kind of surgical procedure is to
- 20 correct the prolapsed organ, therefore to improve the
- symptoms the patient experienced.
- Q. Okay. And you see that the reason for the
- ²³ anterior repair was a grade 1 cystocele?
- 24 A. Yes.
- Q. And the reason for the posterior repair was a

- 1 trying to understand.
- 2 A. Yeah.
- 3 Q. I thought your testimony was, the finding --
- 4 the pathological finding of fibrosis in the lining --
- 5 A. She has two specimens. Okay. One specimen is
- ${\rm 6}~{\rm the}$ -- trim the vaginal mucosa, which does not contain
- 7 any mesh, okay? Because the surgeon, Dr. Harrell, was
- 8 doing prolapse repair. I don't know if you are -- if
- 9 you noticed that.
- MR. VOUDOURIS: Page -51 of your exhibit,
- 11 that's what he's referring to.
- A. And then within that pathology report in the
- 13 microscopic description after the diagnosis, it says
- 14 vaginal mucosa shows fibrosis. This is different from
- 15 the explanted mesh.
- Q. (BY MR. THORNBURGH) Okay. So if we turn to
- page -51, and that's the pathology report that was done
- 18 or performed after the implant procedure at -- on
- 19 specimen removed during the implant procedure?
- A. That's during the implantation.
- Q. Okay. What's the lamina propria?
- A. Lamina propria means underneath the squamous
- 23 mucosa. That's the connective tissue layer.
- Q. And where was this tissue removed from?
- A. That's from the vagina.

- 1 grade 2 rectocele?
- 2 A. Right.
- 3 Q. Okay. And if you look at this -- and also
- 4 during this procedure is when the TVT was implanted,
- 5 right?
- 6 A. Yes.
- 7 Q. And do you have an understanding of where the
- 8 TVT device would have been implanted in Ms. Corbet?
- 9 A. Just --
- 10 MR. VOUDOURIS: Objection.
- 11 Go ahead.
- A. Just underneath the urethra area and within
- 13 the vagina.
- Q. (BY MR. THORNBURGH) A different location than
- 15 where the grade 1 cystocele and grade 2 rectocele were
- 16 identified?
- 17 A. That means one is anterior for -- for
- 18 cystocele, that means the bladder prolapsed into the
- 19 vagina or bulging into vagina. Then rectocele is the
- 20 rectum bulging to the vagina.
- Q. Well, you would agree that the surgery that
- 22 occurred to repair the grade 1 cystocele would have been
- 23 in a different -- different anatomical location than
- 24 where the TVT mesh was implanted?
- MR. VOUDOURIS: Objection; form.

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1	A. I disagree, because the overall, this is all	1	certain degree of vaginal atrophy. That's very
2	vagina. It's considered an organ is within the	2	reasonable.
3	vagina.	3	Q. (BY MR. THORNBURGH) Let's look at the implant
4	Q. (BY MR. THORNBURGH) Do you	4	operative report. Do you see it says in this report,
5	A. So therefore, it's the same location. But	5	it says, "A linear incision was made at the apex into
6	within the vagina, you have different location, that	6	the cystocele with a knife and Metzenbaum scissors were
7	will be fine.	7	used to develop the cystocele with blunt and sharp
8	Q. Well, do you have an understanding that a	8	dissection" [as read].
9	rectocele or a cystocele can cause inflammation?	9	Did I read that accurately?
10	MR. VOUDOURIS: Objection; form,	10	A. Yeah.
11	foundation.	11	Q. And then it goes on to say that a suture was
12	A. Rectocele and cystocele depends on the degree.	12	placed around the cystocele. Do you see that?
13		13	A. Yes.
14		14	Q. "And then it was tied down and the cystocele
15		15	reduced" [as read].
16	Q. (BY MR. THORNBURGH) Okay. So you agree that	16	Did I read that correctly?
17	a anterior or a rectocele can cause inflammation?	17	A. Yes.
18	MR. VOUDOURIS: Object to form.	18	Q. And then it says, "Excess vaginal mucosa was
19	A. Anterior is cystocele. Posterior is	19	excised" [as read]?
20	rectocele, first of all.	20	A. Correct.
21	Q. (BY MR. THORNBURGH) Right, right.	21	Q. All right. And is it your understanding based
22	A. Yeah. If they have certain degree, reach to a	22	on reviewing this report and based on your knowledge,
23	certain degree of severeness, then inflammation may	23	training, and experience, that the excess vaginal mucosa
	occur.	24	was removed at the location of where the cystocele was
25	Q. What degree or grade of a rectocele can cause		located?
	Page 131		Page 133
	inflammation?		
		1	A. Correct. It's part of vagina.
2	MR. VOUDOURIS: Objection; form and	2	Q. Okay. And you don't know one way or the other
3	MR. VOUDOURIS: Objection; form and foundation, beyond the scope.	2 3	Q. Okay. And you don't know one way or the other whether or not the cystocele can cause inflammation?
3 4	MR. VOUDOURIS: Objection; form and foundation, beyond the scope. A. And, again, I I'm not a surgeon, number	2 3 4	Q. Okay. And you don't know one way or the other whether or not the cystocele can cause inflammation? MR. VOUDOURIS: Objection; form and
3 4 5	MR. VOUDOURIS: Objection; form and foundation, beyond the scope. A. And, again, I I'm not a surgeon, number one. And I do not perform these surgeries. And what	2 3 4 5	Q. Okay. And you don't know one way or the other whether or not the cystocele can cause inflammation? MR. VOUDOURIS: Objection; form and foundation.
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3 4 5 6 7	MR. VOUDOURIS: Objection; form and foundation, beyond the scope. A. And, again, I I'm not a surgeon, number one. And I do not perform these surgeries. And what I my expertise is within the pathology field. So I think these questions are best answered by the surgeon.	2 3 4 5 6 7	Q. Okay. And you don't know one way or the other whether or not the cystocele can cause inflammation? MR. VOUDOURIS: Objection; form and foundation. A. That's what I already say. The cystocele, if to a certain degree if they're protruding out
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25

25 based on that pathology report, I can say she has

MR. VOUDOURIS: Objection; form.

	Page 134		Page 136
1	A. Urethra is the opening close to the clitoris	1	A. That's not related to the pathologist
2	area in the vagina.	2	specimen.
3	Q. (BY MR. THORNBURGH) Okay. So that's going to	3	Q. Okay. Then going down a couple lines, it
	be a different location than where the excess vaginal	4	talks about the repair of the rectocele. It says, "A
5	mucosa was excised, right?	5	rectocele was developed in the suture was placed around
6	A. That's correct.	6	it" [as read].
7	Q. It says, "At the distal urethra location,	7	Do you see that?
8	there was an incision made and the suburethra" [as	8	A. Yes.
9	read] strike that.	9	Q. It goes on to say it was tied down and
10	It says that, "At the urethra meatus an	10	reduced, meaning they they repaired the rectocele
11	incision was made suburethrally approximately two	11	A. Posterior part.
12		12	Q posterior?
13	laterally. Injection was placed in the retropubic space	13	And it says, "Excess vaginal mucosa was
14	both transabdominally and transvaginally" [as read].	14	excised and reapproximated with a running lock of three
15	Do you see that?	15	vicryl" [as read].
16	A. Yes.	16	Do you see that?
17	Q. And do you have an understanding that the	17	A. Yes.
18	retropubic space is the location where the TVT device	18	Q. Okay. Do you understand have an
19		19	understanding that that procedure would have been in the
20	A. Yes. That's the right place.	20	posterior?
21	Q. And it goes on and describes the rest of the	21	A. That's that's for the posterior repair.
22	TVT procedure, right?	22	Q. At the location of the cystocele I'm sorry,
23	A. Yeah.	23	at the location of the rectocele?
24	MR. VOUDOURIS: Objection.	24	A. At the location of the rectocele.
25	Q. (BY MR. THORNBURGH) Including, you know,	25	Q. Okay. And if we turn the page to the
	Page 135		Page 137
1	following the manufacturer's guidelines, right	1	pathology report dated July 14th, 2011, it says under
2	A. Yes.		do you see the vaginal or final diagnosis, and it
3	Q to perform the procedure?		says, "Vaginal tissue with mild chronic inflammation of
4	And then the similar procedure was		lamina propria" [as read]?
	performed on the other side	1 -	
_		5	
6		5	A. Yes.
6 7	A. Correct.	5 6 7	A. Yes.Q. Okay. And it's your understanding that was
7	A. Correct. Q right?	7	A. Yes.Q. Okay. And it's your understanding that wasthe location of the of the tissue that was strike
7 8	A. Correct.Q right?All right. And then it goes on to say,	7 8	A. Yes. Q. Okay. And it's your understanding that was the location of the of the tissue that was strike that.
7 8 9	A. Correct. Q right? All right. And then it goes on to say, "There was no" I'm sorry. It goes on to say	7 8 9	A. Yes. Q. Okay. And it's your understanding that was the location of the of the tissue that was strike that. The tissue that was sent for pathology was
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		Page 138		Page 140
	1	Then in the lower estrogen levels, then	1	atrophic-related changes, yes. If there's no other
	2	vagina becomes atrophic, it changes, even in the certain	2	contraindication for hormone replacement, then hormone
	3	degree of estrogen replacement or hormone replacement.	3	replacement will be offered.
	4	Then that will be depending on the time of replacement,	4	MR. SNOWDEN: He needs to change the tape.
	5	the length of replacement, the dose of replacement.	5	MR. THORNBURGH: Okay. Go ahead.
	6	So then if the atrophy already being	6	THE VIDEOGRAPHER: We're off record at
	7	induced, then it is difficult to completely recover or	7	1:54 p.m., end of Tape 2.
	8	back to the normal situation. Just like in	8	(Break taken.)
	9	postmenopausal woman, you want to go back to 30 years	9	THE VIDEOGRAPHER: We're back on record at
1	L O	old reproductive age, it's unlikely.	10	2:05 p.m., beginning Tape 3.
	11	Q. (BY MR. THORNBURGH) So is it your opinion	11	Q. (BY MR. THORNBURGH) Doctor, before we went
	12	that based on this pathological finding, that	12	
	13	Mrs. Corbet had some degree of vaginal atrophy?	13	
	L4	A. Correct.	14	A. Corbet.
	15	Q. Do you know what degree of vaginal atrophy is	15	Q had regarding sorry. Strike that.
		described here?	16	Before we went off the record, before we
	L 7	A. I can't give what the degree or how much	17	took a break, I asked you what risk factors Ms. Corbet
				•
	L8	degree of atrophy had. But the yes, based on this	18	had that you thought could increase the risk of
	L9	fibrosis finding, it should be if the finding is	19	mesh-related complications. And we had gone through a
	20	true, then vaginal atrophy is there.	20	list: She didn't have diabetes, she didn't have
	21	Q. And are there medications that can be taken to		wasn't a smoker, she wasn't obese, right?
	22	treat vaginal atrophy?	22	A. Correct.
	23	MR. VOUDOURIS: Objection.	23	Q. And then you identified vaginal atrophy as a
	24	Q. (BY MR. THORNBURGH) Let me ask a question:		risk factor that Mrs. Corbet had; is that correct?
2	25	Did Mrs a different question, I'll withdraw the last	25	A. Correct.
- 1				
Г		Page 139		Page 141
	1	Page 139 one.	1	_
	1 2	· · · · · · · · · · · · · · · · · · ·	1 2	MR. VOUDOURIS: Objection.
		one.		_
	2	one. Did Mrs. Corbet was Mrs strike that.	2	MR. VOUDOURIS: Objection. Q. (BY MR. THORNBURGH) And did you identify other than strike that.
	2 3 4	one. Did Mrs. Corbet was Mrs strike	2 3	MR. VOUDOURIS: Objection. Q. (BY MR. THORNBURGH) And did you identify other than strike that. Other than the vaginal atrophy, did you
	2 3 4	one. Did Mrs. Corbet was Mrs strike that. Was Mrs. Corbet prescribed medications to that typically treat vaginal atrophy?	2 3 4	MR. VOUDOURIS: Objection. Q. (BY MR. THORNBURGH) And did you identify other than strike that. Other than the vaginal atrophy, did you identify any other risk factor for a mesh-related
	2 3 4 5 6	one. Did Mrs. Corbet was Mrs strike that. Was Mrs. Corbet prescribed medications to that typically treat vaginal atrophy? MR. VOUDOURIS: Objection; form and	2 3 4 5	MR. VOUDOURIS: Objection. Q. (BY MR. THORNBURGH) And did you identify other than strike that. Other than the vaginal atrophy, did you identify any other risk factor for a mesh-related complication?
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Page 142 Page 144 1 MR. VOUDOURIS: You said 50. 1 patient received three procedures, right, anterior MR. THORNBURGH: Oh. 58-year-old female. 2 2 repair, posterior repair, and TVT implantation. So this 3 A. Correct. 3 area of granulation tissue can either represent delayed Q. (BY MR. THORNBURGH) And the postop -- this 4 4 healing process or recent injury by her -- any sexual 5 postop visit was related to a follow-up for her anterior activity or something like that. These -- all things 6 repair, her posterior repair, and the TVT, right? can happen -- can cause this granulation tissue. 7 A. Yes. Q. (BY MR. THORNBURGH) Is it -- is it -- is one Q. You see here in this paragraph it says, "She of the things that might -- is -- strike that. 9 has voiding and control better with sancturra and Valium Is it possible that for Mrs. Corbet one of 10 and still has occasional spontaneous leak. Complain of the possible explanations for the granulation tissue pain with sex and urge to deficate with sex. Has had that was identified on October 12th, 2011, is also the vaginal bleeding with sex. Less each time" [as read]. placement of the TVT device that she had implanted three 13 Do you see that? months prior? 13 14 14 A. Yes. MR. VOUDOURIS: Objection; form, Q. So this is three months postop -- postimplant 15 15 foundation. 16 procedure, right? 16 A. I have no comment on that. I think the best 17 A. Yes. From July to October. person to answer this question will be the surgeon, 18 Q. Okay. And she's reporting for the first time 18 Dr. Smith. 19 a complaint with pain during intercourse, right? 19 Q. (BY MR. THORNBURGH) Okay. So you're not MR. VOUDOURIS: Objection. 20 going to offer an opinion one way or the other regarding 21 A. Based on this report. the granulation tissue; is that fair? Q. (BY MR. THORNBURGH) And also bleeding with A. That's why I say granulation tissue overall is 22 22 23 intercourse, right? 23 related to the injury and delayed healing process. 24 A. Right. 24 That's it. 25 25 Q. Okay. And then also, it says that she --Q. Other than that, you're not going to come in Page 143 Page 145 1 "There was a small -- small area of granulation tissue 1 at trial and try to offer an opinion regarding what the with vaginal -- vag mildly tender mass on one from 2 cause of the granulation tissue was that was identified abdominal wall to 5 o'clock and vag moblie" [as read]. 3 three months after the mesh implant? A. No. Do you see that? 5 A. Yes. Q. Okay. No, you're not going to offer those Q. Okay. So what -- what is granulation -- what opinions, right? 7 is granulation tissue? A. No. 8 A. Okay. 8 Q. Is -- for Mr. Way, was placement of the 9 9 mesh --MR. VOUDOURIS: Objection. 10 A. Granulation tissue is the term -- as a 1 0 MR. VOUDOURIS: Objection. 11 pathology term -- describing the wound healing, okay? 11 MR. THORNBURGH: Sorry. 12 Q. (BY MR. THORNBURGH) For Mrs. Corbet -- sorry. 12 Any injury or surgical procedures is considered as an 13 injury for tissue. Then during the healing process, if 13 For Mrs. Corbet, was placement of mesh 14 the healing process does not heal well, then you have a -- also a risk factor for erosion? 15 granulation tissue. Okay. Granulation tissue is 15 MR. VOUDOURIS: Objection; form, composed by fibroconnective tissue, vessels, and foundation, beyond the scope. 16 17 17 inflammation. A. Based on literature findings, mesh exposure or 18 Q. (BY MR. THORNBURGH) And -- and do you also erosion is a lower complication rate. Overall, it's 19 have an understanding based on your review of the about maybe three percent or less, okay? So therefore, 20 records that you reviewed in this case that granulation implantation of the mesh to correct stress urinary tissue is also an indication of a tissue response to incontinence, basically is a -- has a lower rate for 22 synthetic polypropylene mesh? 22 this kind of complication, that's the overall situation. 23 MR. VOUDOURIS: Objection; form 23 Q. Well, isn't it true, though, that if

A. This one can be totally unrelated, because

24 foundation.

25

Mrs. Corbet did not have mesh implanted, she wouldn't

have experienced a mesh erosion?

Case 2:12-md-02327 Document 2834-4 Filed 09/19/16 Page 39 of 73 PageID #: 98316 Wenxin Zheng, M.B. Page 146 Page 148 1 MR. VOUDOURIS: Objection. 1 observed. So it's not like just a -- a yes-or-no 2 A. If no mesh -- no mesh exposure, that's for 2 answer. 3 sure. However, if any woman -- postmenopausal woman, Q. (BY MR. THORNBURGH) Was it -- was it significant to you that before Mrs. Corbet had the mesh 4 even without any implants or mesh or other things, then they still may experience ulceration or laceration or implanted, she didn't have any complaints of dyspareunia other things or injury. 6 or pelvic pain? 7 MR. THORNBURGH: Motion to strike MR. VOUDOURIS: Objection; form, beyond nonresponsive. the scope. Q. (BY MR. THORNBURGH) My question simply was: 9 A. Yeah, that's a clinical complaining. Then 10 If she didn't have mesh implanted, she wouldn't have had also, she experience some kind of bleeding also. 11 mesh erosion? 11 Q. (BY MR. THORNBURGH) There's --12 MR. VOUDOURIS: Objection; asked and 12 A. Right. 13 answered. 13 Q. Well, your --14 14 Q. (BY MR. THORNBURGH) Right? A. So that's --15 A. Yeah. Correct. 15 Q. -- related to her hysterectomy, but my 16 Q. Now, eventually, Mrs. Corbet went to see question to you is: Was it significant in your mind or 17 Dr. Smith, right? did you consider, in rendering your opinions, the fact 18 A. Yes. that she did not have any symptoms or complaints 19 Q. And do you have a recollection of why regarding painful intercourse prior to having the mesh 20 Mrs. Corbet went to see Dr. Smith? implanted? 20 21 21 A. Based on Dr. Smith's deposition, she MR. VOUDOURIS: Objection; form, 22 complained of dyspareunia, then she went to see her. foundation, beyond the scope, compound. 23 23 Q. In fact, if you -- if you look at Exhibit 7, A. Again, this is a clinical symptoms. I do not 24 there's a letter from Dr. Smith to Dr. Harrell rely on these clinical symptoms then, you know, use 25 concerning her evaluation of Ms. Corbet, right? Do you these clinical findings to interpret my pathological Page 147 Page 149 1 remember seeing that letter? 1 findings. That's for sure. 2 MR. VOUDOURIS: Page? Q. (BY MR. THORNBURGH) So I'm just trying to 3 A. Can you tell me the page number, please? determine whether or not I need to ask you any questions Q. (BY MR. THORNBURGH) Page 26 -- no, it's not, 4 about the medical records. Let me -- let's talk about 5 sorry. Page 27. this one. So this record is dated January 31st, 2013, 6 I mean, maybe this saves us some time. 6 Bates number -27. Have you seen this record before? 7 Did you consider these records in reaching your opinion A. Yes. Q. Okay. And do you recognize this is a letter in your case? 8 9 9 from her -- eventually her explanting physician, MR. VOUDOURIS: Objection. 10 A. I -- I want to read and understand the 10 Dr. Smith, to the implanting physician, Dr. Harrell? 11 clinical situation, that's true. But many pure 11 A. Yes. 12 12 clinical-related information, I may not be qualified to Q. Do you see where it says that Ms. Corbet was 13 answer because I'm a pathologist. evaluated for severe overactive bladder and recent Q. (BY MR. THORNBURGH) Okay. Because I don't bleeding episodes? 15 want to -- you know, I don't want to go over things that 15 A. Yes; that's the chief complaint. 16 you didn't rely on in reaching your opinions in this 16 Q. Okay. Did you have an understanding that case. So to the extent that you didn't consider and those conditions or symptoms occurred at some point 18 rely on the medical records in this case, it may save us after placement of the TVT device? 18 19 19 some time. MR. VOUDOURIS: Objection. 20 So did you consider these records in 20 A. From time -- time consideration, yes, her --21 reaching your opinions or not? 21 this finding is after TVT implantation.

22

23

24

25

chief complaint?

A. Yes.

Q. What is the chief complaint?

25 my opinion mainly rely on the histological findings I

22

24

23 answered

MR. VOUDOURIS: Objection; asked and

A. The medical records will be useful for me, but

Q. (BY MR. THORNBURGH) Okay. And do you see the

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	Page 150		Page 152
:	A. That's the main complaint, the main feeling	1	A. I'm not sure which sentence which paragraph
2	2 from the patient.	2	you referring.
3	Q. And what does it indicate that her main	3	Q. (BY MR. THORNBURGH) I'll go ahead and mark as
4	4 problem Mrs. Corbet's main problems were on	4	Exhibit Number 8.
Ē	5 January 31st, 2013?	5	A. 8.
6	MR. VOUDOURIS: Objection; form.	6	(Exhibit Number 8 was marked.)
-	A. As you mentioned, it's overactive bladder as	7	Q. I've handed you Exhibit Number 8, which we
8	3 well as dyspareunia.	8	talked about earlier on today, which is the article
2	Q. (BY MR. THORNBURGH) And so it says overactive	9	called "Histopathology of Excised Midurethral Sling
10	bladder and pain in the vagina during intercourse,	10	Mesh" by Hill and others.
11	1 right?	11	MR. VOUDOURIS: Dan, I believe they made
12	A. [Nods head.]	12	three copies.
13		13	MR. THORNBURGH: Sorry. That wasn't on
14		14	purpose.
15	5 hematuria?	15	Q. (BY MR. THORNBURGH) It's are you familiar
16	5 A. Yes.	16	with this document?
1		17	A. I have read, but if you asking very specific
18		18	questions, certainly, I have to read again.
19		19	Q. But this is the document that you're referring
20		20	to earlier in today's deposition?
2		21	A. Yes.
22		22	
	C (Q. This is the new document that you provided
23	<i>C</i> , <i>C</i>	23	or which was provided in Exhibit Number 2 as new
24	2		literature that you've reviewed?
25	Q. From what, I'm sorry?	25	A. Correct.
	Page 151		Page 153
:	A. Urine.	1	Q. And which you rely on for purposes of your
2	Q. Okay.	2	opinions in this case?
1 3	A. Urination.	3	A. I don't mean rely on opinion of this, because
4	Q. And are you going to offer any opinions	4	this is a histopathological finding of these explant
[5 concerning hematuria?	5	sling, therefore, it's related to the pathology finding.
6	MR. VOUDOURIS: Objection; beyond the	6	That's the the purpose I read this article.
	7 scope.	7	Q. So this is an article that was published after
	A. I can tell you based on the pathology report	8	you had served your expert report, right?
	that she had benign papilloma, all right, and that	9	A. Correct.
10		10	Q. And it says that, "The purpose or objective of
11		11	
12		12	characteristics of pathological specimens excised mid
13		13	midurethral sling mesh and surrounding vaginal tissue in
١.			
14		14	patients who presented postoperatively with pain and/or"
15		15	[as read]
16	· · · ·	16	MR. VOUDOURIS: Objection. I think it
17		17	says preoperative.
18		18	Q. (BY MR. THORNBURGH) "Present preoperative
19		19	operatively with pain and/or exposure of mesh to
20		20	patients who underwent mesh excision for voiding
2	· ·	21	dysfunction without pain and erosion" [as read].
22	2 voiding dysfunction and overactive bladder disorder	22	Did I read that correctly?
121	associated with inflammatomy response in woman with much	122	A Correct

23

24

A. Correct.

25 study, correct?

Q. And this was a retrospective case control

24 explants, right?

25

23 associated with inflammatory response in women with mesh

MR. VOUDOURIS: Objection.

	wenxin Zn	ler.	ig, M.B.
	Page 154		Page 156
1	A. Yes.	1	MR. VOUDOURIS: Objection.
2	Q. Of 130 patients?	2	A. No. They are reasonably, you know, planned
3	A. Yes.	3	planned for the study.
4	Q. And do you see the do you recall that in	4	Q. (BY MR. THORNBURGH) And you see the result
5	the study, they divided out these patients or their	5	section
6	subjects into three groups?	6	A. Yes.
7	A. Yes.	7	Q in the abstract?
8	Q. Women who had voiding dysfunction without	8	A. Correct.
9	pain, women who had pain and/or exposure, and then women	9	Q. It says, "60, 42 percent, with voiding
10	who had voiding dysfunction with pain and/or mesh	10	dysfunction only. 21 or 16.2 percent with pain/erosion.
	exposure?	11	
12	A. It's a combination, yes.	12	
13	Q. Did you rely on this in any way regarding your	13	
14	opinions concerning Mrs. Corbet's mesh explant or the	14	A. Correct.
	complications from mesh?		
15	-	15	MR. VOUDOURIS: Objection; form.
16	A. I do not rely on what they have found to	16	Q. (BY MR. THORNBURGH) It says, "The voiding
17	generate my opinion, because my opinion has been	17	dysfunction only group was found to have significantly
18	generated before this publication came out.	18	higher levels of inflammation, median grade 2 on a scale
19	Q. Did you consider it, though, in offering your	19	1, 2
20	opinions?	20	A. Yes.
21	MR. VOUDOURIS: Objection; form.	21	Q. "Compared to the other two groups with a P
22	A. I don't think this is relevant, because I did	22	value of .007. There were no statistical differences in
23	not change my opinion at all since last year.	23	fibrosis" [as read].
24	Q. (BY MR. THORNBURGH) Well, Mrs. Way	24	What's fibrosis?
25	Mrs. Corbet had TVT, midurethral sling implanted, right?	25	A. Fibrosis means lots of collagens.
	Daga 155		Daga 157
1	Page 155	1	Page 157
1	A. Yes.	1	Q. It's a scar, right?
2	A. Yes.Q. She as we saw from the medical records, she	2	Q. It's a scar, right? MR. VOUDOURIS: Objection.
2 3	A. Yes. Q. She as we saw from the medical records, she had postimplant voiding dysfunction, right?	2 3	Q. It's a scar, right?MR. VOUDOURIS: Objection.A. No.
2 3 4	A. Yes.Q. She as we saw from the medical records, she had postimplant voiding dysfunction, right?A. Yes.	2 3 4	Q. It's a scar, right?MR. VOUDOURIS: Objection.A. No.Q. (BY MR. THORNBURGH) Scar tissue?
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- $^{\, 1} \,$ findings were with respect to the fibrosis and giant
- 2 cell reaction in these three groups?
- 3 A. They have definition within the table. It
- 4 says histological grading system, chronic inflammation,
- 5 you have, basically -- I think all these things we have
- 6 described.
- Q. Well, actually, do you see where it says -- if
- 8 you go to the table 1, which is the histological grading
- 9 system --
- 10 A. Yeah.
- 11 Q. Did you use this same grading system in your
- 12 analysis of Mrs. -- or similar grading system --
- 13 A. Yes.
- Q. -- in your analysis of Mrs. Corbet?
- A. As I mentioned that, I think, before this
- 16 publication came out, in general, pathologists will use
- 17 similar grading system.
- Q. Okay. And so regarding fibrosis, they have
- 19 basically four grades, right?
- 20 A. Yes, from 0 to 3.
- Q. And they say 0 is no fibrosis?
- 22 A. Right.
- Q. I guess that means no collagen?
- MR. VOUDOURIS: Objection.
- 25 A. No --

1 pathology term.

Q. Okay. If you go to -- see the results section

Page 160

Page 161

- 3 on page 592 of Exhibit 8?
- 4 A. Yes.
 - Q. You see it says, "50 -- 45.4 percent of these
- 6 patients underwent mesh excision for voiding
- 7 dysfunction" [as read].
- 8 Did I read that accurately?
- 9 A. Yes.
- Q. And then, "16.2 percent underwent excision for
- 11 both pain and exposure and voiding dysfunction. And the
- 12 remaining 49, or 37.7 percent, underwent surgical
- 13 excision for both pain, exposure, and voiding
- 14 dysfunction" [as read].
- 15 A. Correct.
- Q. Almost 40 percent underwent surgical excision
- 17 for pain, exposure, and voiding dysfunction?
- 8 A. Correct.
- Q. And would that be the group that Mrs. Corbet
- 20 would have been in if she was involved in this study?
 - MR. VOUDOURIS: Objection; form.
- Q. (BY MR. THORNBURGH) In other words, is
- 23 that -- is that -- is that the -- I'll withdraw that
- 24 question.

21

25 A. Okay.

Page 159

- Q. (BY MR. THORNBURGH) No fibroconnective
- 2 tissue?
- 3 A. Yeah, mainly fibroconnective tissue.
- 4 Q. Mild would be predominantly loose connective
- 5 tissue with focal fibrosis?
- 6 A. Yes.
- O. And then moderate was focal dense fibrosis.
- 8 And then marked as dense fibrosis with formation of
- 9 fibrous nodule plaque?
- 10 A. Correct.
- Q. And then for their inflammation, they, again,
- 12 have a grading system based on no inflammatory cells,
- 13 sparse chronic inflammatory infiltrate, confined areas
- 14 of giant cell reaction, moderate is chronic inflammation
- 15 infiltrate in areas of giant cell reaction involving
- 16 adjacent connective tissue?
- 17 A. Correct.
- Q. Okay. And marked would be the highest on the
- scale, which would be marked inflammatory infiltrate in
- 20 areas of giant cell reaction and prominently involving
- 21 connective tissue, any germinal center formation?
- 22 A. Correct.
- Q. What's germinal -- germinal center formation?
- A. It's a lymphoid aggregates, like within the
- 25 lymphoid tissue, you have germinal center. It's a pure

- Q. If you go to the next page --
- 2 A. Yes.
- Q. -- most common finding in all groups is mild
- 4 inflammation, 53 percent?
- 5 A. Yes.
- 6 Q. Then it says, "Only 9.2 percent of specimens
- 7 showed no inflammation" [as read].
- 8 So very little of the explant showed no
- 9 inflammation, right?
- MR. VOUDOURIS: Objection.
- 11 A. 10 -- about 10 percent, yeah.
- Q. (BY MR. THORNBURGH) Moderate or marked
- 13 inflammation was noted in 48 or 39 -- 36.9 percent of
- 14 the specimens, right?
- 15 A. Correct.

- Q. And then the specimens in the voiding
- 17 dysfunction only group found to have higher amounts of
- 18 moderate inflammation.
 - And then it talks about the fibrosis. It
- 20 says in the next paragraph, it says, "Moderate fibrosis
- 21 was seen in 61 percent of pathological specimens with no
- 22 difference found between the three groups" [as read]?
- 23 A. Correct.
- Q. Did I read that correctly?
- 25 A. Yes.

	WCIIXIII ZI		
	Page 162		Page 164
1	Q. And so they're saying that in the cohort that	1	A. I'm not going to render my opinion regarding
2	they looked at of 160 something patients	2	these material weight issues.
3	A. 130.	3	Q. So this study found that 60 percent of all the
4	Q. 170?	4	explants had moderate fibrosis?
5	A30.	5	A. Yes.
6	Q. 130. In that cohort, 61 percent, greater than	6	Q. Which is fibroconnective issue?
	half of those patients, specimens demonstrated moderate	7	MR. VOUDOURIS: Objection.
8	fibrosis in all groups?	8	A. Which, yes, within the fibroconnective tissue.
9	A. Correct.	9	Q. (BY MR. THORNBURGH) And if you look over to
10	Q. And that almost all of the specimens that they	10	the next page, 594, there are some figures where they
11	looked at demonstrated giant cell reaction?	11	describe the different grades by showing
12	MR. VOUDOURIS: Objection to form.	12	microphotographs of explant specimens, right?
13	A. That's a common finding.	13	A. Correct.
14	Q. (BY MR. THORNBURGH) It's a common finding to	14	Q. Okay. And do you have any disagreement with
15	observe	15	the depiction in their microphotographs of the way they
16	A. From explanted mesh specimen.	16	graded the their explant specimens?
17	Q. Do you see the discussion section, it says,	17	A. No.
18	"The optimal implant into human tissue has been	18	MR. VOUDOURIS: Objection; broad.
19	described as one that does not illicit a significant	19	A. I I agree, because I use similar grading
20	post-tissue reaction, is lightweight, maintains	20	system and also use similar representative pictures.
21	flexibility, and provides long-term support" [as read]?	21	Q. (BY MR. THORNBURGH) In your experience
22	MR. VOUDOURIS: Is there a question?	22	strike that.
23	Q. (BY MR. THORNBURGH) Do you see do you see	23	Based on this grading system strike
24	that section?	24	that. I'm going to I'm going to try to skip through
25	A. I see the sentence, yes.	25	it.
	Page 163	+	Page 165
1	Q. Okay. And	1	Do you see additionally on the right on
2	MR. VOUDOURIS: Dan, you know	2	the right side of page 594
3	MR. THORNBURGH: This is a new this is	3	A. Second paragraph?
4	a new publication.		
5	a new paoneation.	4	Q. Yeah. It says, "Presence" it says, "One
1	MR. VOUDOURIS: No, I'm not I'm not	4 5	
6		5	Q. Yeah. It says, "Presence" it says, "One
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		Page 166		Page 168
		offer at trial?		already
	2	MR. VOUDOURIS: Objection. All of these	2	MR. THORNBURGH: Smith?
	3	areas were covered extensively in his other deposition.	3	MR. VOUDOURIS: It's an exhibit to his
	4	Q. (BY MR. THORNBURGH) At least these authors	5	r · r
		are indicating that voiding dysfunction in women		MR. THORNBURGH: Oh. He testified he testified earlier that it was a new article that he was
		implanted implanted with midurethral slings could be	6	
		a symptom of the inflammatory response causing retraction or shrinkage of the scar tissue around the	7	providing on Exhibit 2. That's what he testified to. The date of this article is
	9	mesh, right?	9	MR. VOUDOURIS: Hold on.
	10	MR. VOUDOURIS: Objection; form,	10	MR. THORNBURGH: 2013. I wasn't going
		foundation		to ask all I'm doing is marking it for the purpose of
	12	A. I I don't have	12	the record since he since he testified about it
	13	MR. VOUDOURIS: speculation.	13	
	14	A any evidence from based on the	14	MR. VOUDOURIS: That's fine. If you're
		histological findings from many explanted sling I	15	just going to mark it for purposes of the record
		observed. I don't have evidence to support	16	MR. THORNBURGH: Yeah.
	17	Q. (BY MR. THORNBURGH) I think they're	17	MR. VOUDOURIS: that's fine.
	18	A that statement.	18	THE WITNESS: Right. That's fine.
	19	Q. I think what they're suggesting is that the	19	MR. THORNBURGH: Do you want a copy of it?
	20	evidence would be based on a clinical symptom of voiding	20	MR. VOUDOURIS: Sure. And this is going
	21	dysfunction, right?	21	to be 10.
	22	MR. VOUDOURIS: Objection	22	MR. MORRIS: 9.
	23	A. Therefore	23	MR. THORNBURGH: 9.
	24	MR. VOUDOURIS: hypothesis, form,	24	MR. VOUDOURIS: Hill was 8?
	25	foundation.	25	THE REPORTER: Yes.
-		D 445	-	D 450
	1	Page 167	1	Page 169
	1	A. Therefore, we are talking two different	1	Q. (BY MR. THORNBURGH) Was that the article that
	2	A. Therefore, we are talking two different things. And my opinion mainly based on the pathological	2	Q. (BY MR. THORNBURGH) Was that the article that you were referencing earlier?
	2	A. Therefore, we are talking two different things. And my opinion mainly based on the pathological findings.	2 3	Q. (BY MR. THORNBURGH) Was that the article that you were referencing earlier? A. Correct.
	2 3 4	A. Therefore, we are talking two different things. And my opinion mainly based on the pathological findings. Q. (BY MR. THORNBURGH) Is it your are you	2 3 4	Q. (BY MR. THORNBURGH) Was that the article that you were referencing earlier?A. Correct.Q. And you've already provided testimony in
	2 3 4 5	A. Therefore, we are talking two different things. And my opinion mainly based on the pathological findings. Q. (BY MR. THORNBURGH) Is it your are you saying that another expert like a urogynecologist should	2 3 4 5	 Q. (BY MR. THORNBURGH) Was that the article that you were referencing earlier? A. Correct. Q. And you've already provided testimony in another case concerning that that article?
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- 1 and you were asked questions about it. So that --
- 2 THE WITNESS: Oh, I may forgot.
- 3 MR. VOUDOURIS: That -- to use a term we
- 4 used earlier, that's a field that's already been plowed.
- THE WITNESS: Okay. Sorry for this. I 5
- was confused, maybe. 6
- Q. (BY MR. THORNBURGH) And I'm not going to ask
- you any questions.
- A. Okay. 9
- Q. I just want to mark it for the record. 10
- 11 A. Okay.
- 12 Q. Okay. Let's -- let's turn to your -- your
- 13 expert report.
- 14 A. Sure.
- 15 Q. And I believe most of your report, your
- 16 general report has already been -- you've already been
- 17 questioned about it at prior depositions, right?
- 18 A. Yes.
- 19 Q. So I'm going to turn your attention to page 9,
- 20 which is section 2 of your report. It says, "Opinion
- 21 specific to plaintiff Kathryn Corbet" [as read].
- 22 A. Okay.
- 23 Q. And so the -- you have a section here under
- 24 the subsection (a) called patient history.
- A. Yes.

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- Q. And we've gone through some of that history
- 2 briefly, but was any of this --
- 3 MR. VOUDOURIS: Objection.
- Q. (BY MR. THORNBURGH) Was any -- any of these
- 5 findings, the history findings, relevant to your final
- 6 conclusions or opinions in this case?
- 7 A. Yes.
- Q. Okay. What findings in the patient history 8
- 9 section of your expert report were significant to your
- 10 opinions that you're offering in this case, clinical
- 11 findings?
- 12 A. I think for the clinical findings when I write
- 13 a report, I have to understand the whole situation,
- 14 right, and what's the history and how those things
- 15 happens. Then that's the -- that's the normal
- 16 procedure.
- 17 It's not necessarily saying when I write
- 18 down those patient history, then all these points I have
- 19 to be used for -- to generate my opinion. Okay. That's
- 20 the overall situation. So you're asking me which part
- 21 or which sentence I have used significantly for my
- 22 opinion, I think I am not able to answer this particular
- 23 question.
- 24 Q. Was the explant report significant to your
- 25 opinion in this case?

- A. Yes. And the pathology finding is the -- is
- 2 the main finding, then my opinion will generate --
- 3 basically generated based on the pathological
- observation and examination.
- Q. I'm just going to mark this exhibit and we're
- going to look at the explant report really quick.
 - (Exhibit Number 10 was marked.)
- Q. I marked as Exhibit Number 10 the explant
- report of -- I'm sorry. I marked as Exhibit Number 10
- the medical records from PennUrology for Mrs. Corbet.
- 11 And we already looked at the January 2013
- 12 record from -- from Dr. Smith to Dr. Harrell.
- 13 A. Yes.
- 14 Q. So why don't we just go ahead and look at the
- operative report regarding the explant procedure. It's
- on page 2 of Exhibit 10.
- 17 A. That's from Dr. Smith, right?
- 18 Q. Yeah. Do you see it?
- 19 A. Yes.
- 20 Q. Do you see where it says, "Preoperative
- diagnosis, eroded mesh, overactive bladder, and
- macroscopic hematuria" [as read]?
- 23 A. Yes.
- 24 Q. And so that -- it says that the procedure that
- was done was a cystoscopy, bladder biopsy, fulguration,

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- 1 excision of eroded -- the vagina mesh and urethrolysis,
- 2 right?
- A. Yes.
- Q. And it says that, "Mrs. Corbet, a 59-year-old
- 5 female, with a history of TVT sling and a cystocele
- 6 repair, presented vaginal pain and was found on
- 7 examination -- physical examination to have eroded
- 8 vaginal mesh in the left lateral fornix of the vagina"
- [as read], right?
- 10 A. Yes.
- 11 Q. And she also had overactive bladder symptoms
- 12 and microscopic hematuria, and therefore a cystoscopy
- was planned, right?
- A. Yes.
- Q. And so this is the procedure where the mesh
- was removed as well as a -- some other pathological
- tissue, a bladder biopsy, and sent to --
- 18 A. Pathology.
- 19 Q. -- pathology, right?
- 20 A. Correct.
- Q. It says -- if you look at -- on page Bates
- number ending in -3, halfway down, it says, "Vaginal
- exposure was then allowed to be visualized of the left
- 24 arm of the sling coming through the vaginal wall" [as
- 25 read], right?

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	Page 174		Page 176
1	A. Yes.	1	MR. VOUDOURIS: Sure.
2	Q. An excision was made above and below the	2	THE VIDEOGRAPHER: Off the record.
	sling?	3	(Break taken.)
4	A. Yes.	4	THE VIDEOGRAPHER: We're back on record at
5	Q. And and		2:54 p.m.
6	MR. VOUDOURIS: Again, Counselor, we're	6	Q. (BY MR. THORNBURGH) Okay. So you're looking
7		7	at your expert report, which is marked as Exhibit
8	been dictated.	8	Number 2, and you had indicated that in response to my
9	MR. THORNBURGH: I I get it. I get it.	9	question whether or not you considered or reviewed the
10	MR. VOUDOURIS: You're asking him what	10	pathological findings of the nonmesh-related tissue that
11	he's saying.	11	was explanted, and you said, yes, it's in my report.
12	Q. (BY MR. THORNBURGH) What and do you do	12	Can you point me out point to in your report and tell
13	you understand that she went above and below the sling	13	me where that's located?
	to make sure that she captured all of the mesh so	14	A. Okay. So basically, that's in the gross
15	that all enough tissue and mesh to be sent to		finding. I said
16	pathology?	16	Q. What page are you on?
17	MR. VOUDOURIS: Objection; form.	17	A. That's on Page 10, gross finding. All right.
18	A. She I think based on this sentence, her	18	First second line, first batch includes three H&E
19	surgical procedure notes, she covers or removes the	19	slides, all right, labeled SB13-1565, A1, B1, and C1.
20	exposed area and a portion of the mesh in the left side.	20	And then later on, I say slide C1 represent excised
21	Q. (BY MR. THORNBURGH) And there was only		mesh, while A1 and B1 were from bladder biopsies.
	left only the left side up to the midline	22	Q. Okay. So
23	A. Correct.	23	A. And then because bladder biopsy is not really
24	Q was removed, right?		related to the explanted mesh, therefore, I do not
25	A. Correct.	25	provide microscopic finding for these A1 and B1 slide,
	Page 175		Page 177
1	Q. And so is it fair to say that Ms. Corbet	1	but I did review the slides. That's why I clearly
2	continues to have mesh in her body?	2	remember there is a papilloma issue there.
3	A. Yes.	3	Q. Okay. So is it your testimony that you
4	Q. And you're not going to offer any opinions	4	actually looked at those pathological slides under a
5	about the mesh that remains in her body, correct?	5	microscope but didn't take photomicrographs and put them
6	MR. VOUDOURIS: Objection; beyond the	6	in your report?
7	scope.	7	A. Correct
8	A. Correct.	8	Q. Were they produced
9	Q. (BY MR. THORNBURGH) And, ultimately, this is	9	A because it's irrelevant.
10	, , , , , , , , , , , , , , , , , , , ,	10	Q. Were they produced as part of Exhibit
11	analyzed?	11	Number 2?
12	A. I have received the slides from this specimen.	12	A. The pictures in Exhibit Number 2 does not
13	Q. And you only analyzed the slides related to	13	include pictures from A1 and B1, bladder biopsies,
14	the mesh and the mesh and the tissue attached to the	14	because I did not take any.
15	mesh, right?	15	Q. Where are those microphotographs located?
16	MR. VOUDOURIS: Objection; form.	16	MR. VOUDOURIS: Objection.
17	A. And also, I I reviewed bladder biopsy too.	17	A. That's in the thumb drive, right?
18	Q. (BY MR. THORNBURGH) I didn't I didn't see	18	Q. (BY MR. THORNBURGH) Oh, okay. I'm sorry.
19	that in your report.	19	MR. VOUDOURIS: I'm confused.
20	A. Oh, it's there.	20	Q. (BY MR. THORNBURGH) I thought you said
21	Q. Okay. Maybe I missed it. So let's look at	21	MR. VOUDOURIS: He he just said he
22	your report.	22	didn't take photographs of
23	MR. VOUDOURIS: It's under gross findings.	23	MR. THORNBURGH: I thought he said he did
24	MR. THORNBURGH: Off the record one	24	take photographs of the bladder biopsy.
25	second.	25	MR. VOUDOURIS: No.
l l			

- 1 A. No.
- Q. (BY MR. THORNBURGH) All right. You looked at
- 3 them but didn't take photographs?
- 4 A. Right.
- 5 MR. VOUDOURIS: Correct.
- 6 Q. (BY MR. THORNBURGH) Gotcha.
- 7 And you did that because you didn't think
- 8 that a bladder -- the condition that she had was related
- 9 to -- in the bladder -- was related to the mesh?
- 10 A. Correct.
- 11 Q. When you looked at that -- that specimen under
- 12 the slide or those specimens regarding the bladder
- 13 biopsy under the microscope, did you look at those in
- 14 regular -- how did you look at those? Was it polarized
- 15 light microscopy or optical microscopy?
- A. No. Just regular routine microscope, light
- 17 microscope.
- 18 Q. I think you testified or you indicated in your
- 19 expert report that you can see polypropylene when
- 20 you -- when you look at the specimen using light
- 21 microscopy or polarized light microscopy; is that right?
- A. In both conditions, we can see if the plastic
- 23 piece of filament is obvious, still remaining in the
- 24 tissue, yes. Use routine microscope also can see that.
- 25 But for small particles, typical it is not clearly
- Page 179
- 1 visible until we use polarized lens.
- 2 Q. Okay. And you didn't look at the biopsy
- 3 slides using polarized lens?
- 4 A. No.
- 5 Q. So if there was a small particle that migrated
- 6 into the bladder causing a calculi, that is something
- 7 that you would not have seen using regular light --
- 8 regular microscopy, right?
- 9 A. I did --
- 10 MR. VOUDOURIS: Objection.
- 11 A. I did not use polarized lens to examine the
- 12 bladder biopsy because I feel there is no reason to do
- 13 that.
- 14 Q. (BY MR. THORNBURGH) Have you ever seen any
- 15 documents or internal documents that discuss particles
- 16 migrating into the bladder --
- MR. VOUDOURIS: Objection.
- 18 A. There --
- 19 Q. (BY MR. THORNBURGH) -- causing a calculi?
- MR. VOUDOURIS: Objection.
- A. There are reports some mesh erosions can be
- 22 erode into bladder, that's true. But this is not for
- 23 Ms. Corbet case.
- Q. (BY MR. THORNBURGH) And so is the bladder
- 25 biopsies that were performed -- or the bladder findings

- Page 180
- that were discussed in the pathology from the explantrelevant at all for your opinions in this case?
- 3 A. Yeah. The reason Dr. Smith did a biopsy
- 4 because she had -- patient had a hematuria, right? Then
- 5 she did a cystoscopy and found a papillary lesion there.
- 6 That's the reason she did a biopsy. And then her
- ⁷ symptom of hematuria can be perfectly explained by the
- 8 pathological finding.
 - Q. Okay. And then -- so if we go to -- back to
- 10 page -- your case specific opinions section on
- 11 Page 20 --
- 12 A. Yes.
- Q. -- you start off basically by criticizing
- 14 Dr. Iakovlev, right?
- MR. VOUDOURIS: Objection.
- Go ahead.
- A. It's not really criticize, I think, because
- 18 Dr. Iakovlev provide his opinion, and then when I read
- 19 through, I feel many of the -- his opinion is incorrect.
- 20 Therefore, I think these are more meaningful or relevant
- 21 to provide the reason why this is incorrect and what is
- 22 my opinion or my reason to -- to say -- you know, to
- ³ provide such a -- such a report, basically.
- Q. (BY MR. THORNBURGH) You say that he
- tries -- that Dr. Iakovlev tries to use CK -- Figure CK5
 - Page 181
- 1 and CK6 to generalize that the pain complained by
- ² Ms. Corbet is caused by these histological findings.
- 3 And then you go into the next section of your report
- 4 sort of rebutting Dr. Iakovlev's opinions, right?
- 5 A. Yes.

1.0

- 6 Q. Okay. And did you disagree with the findings
- ⁷ observed by Dr. Iakovlev in CK -- Figure CK5 or CK6?
- 8 A. Can we --
- 9 MR. VOUDOURIS: Objection; broad.
 - Q. (BY MR. THORNBURGH) Well, you talk about
- 11 how -- you say in this paragraph that the nerve
- 12 fibers -- that -- you say here that Dr. Iakovlev
- described the nerve fibers shown by regular light
- 14 microscopy and S -- S100 staining by assuming these
- 15 nerve fibers represent a single -- or several nerve
- 16 branches growing into the mesh pores.
- So do you disagree with that finding, or
- 18 that observation, from Dr. Iakovlev concerning Figures
- 19 CK5 and CK6?
- 20 A. Then he further states that he -- the spaces
- 21 within the mesh filled with dense collagen scar, which
- 22 anchors and entraps the nerve in their positions. All
- 23 right. Yes, I disagree that.
 - MR. VOUDOURIS: Doctor, you have
- 25 Dr. Iakovlev's report --

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	Page 182		Page 184
1	THE WITNESS: Right.		two-dimensional picture. Within the mesh pore, you need
2	MR. VOUDOURIS: in front of you	2	a three-dimensional picture to show it's inside of the
3	THE WITNESS: Right.	3	1 3 3
4	MR. VOUDOURIS: which has the	4	I'm referring?
5	photographs	5	Q. (BY MR. THORNBURGH) So I think I understand.
6	Q. (BY MR. THORNBURGH) I think we marked it	6	I think when you when you actually look down at the
7	MR. VOUDOURIS: CK5 and CK6.	7	slide
8	Q. (BY MR. THORNBURGH) I think we marked it as	8	A. Right.
9	Exhibit	9	Q is it three-dimensional?
10	A. 5.	10	A. It's this is two-dimensional.
11	Q 5.	11	Q. Well, that's the that's the photograph.
12	A. Yeah. CK5 and 6.	12	A. Right. It's always two-dimensional.
13	(Sotto voce conversation.)	13	Q. Even when you're looking at the slide like
14	MR. VOUDOURIS: I believe they start on	14	this?
15	Page 108 of his report. But there's no question	15	A. Correct.
16	pending.	16	Q. Okay. So your opinion is that because it's
17	THE WITNESS: Yes; those are the	17	two-dimensional, you can't tell whether or not it's
18	questions those are the figures, correct.	18	within the mesh compartments?
19	Q. (BY MR. THORNBURGH) What page are you on,	19	A. Within the pore or outside of pore or just
20		20	adjacent to the mesh.
21	A. That's on the Page 108 of his report.	21	Q. Okay.
22	Q. Okay. So on Page 108 of his report is Figure	22	A. Right.
23	CK5a, right?	23	Q. And so is
24	A. Right.	24	A. It would be
25	Q. And Dr. Iakovlev writes under the figures that	25	Q. Is that your criticism regarding
	6		
	Page 183		Page 185
1	Page 183 most nerves can be seen by any stain.	1	Page 185 A. This is my my opinion. It's not a
1 2	most nerves can be seen by any stain. Do you agree with that?	1 2	A. This is my my opinion. It's not a
	most nerves can be seen by any stain.		A. This is my my opinion. It's not a
2	most nerves can be seen by any stain. Do you agree with that?	2	A. This is my my opinion. It's not a criticism, okay. It's a statement. Okay. Number two is, these are peripheral
3	most nerves can be seen by any stain. Do you agree with that? A. Yeah. Most nerves are visible without	3 4	A. This is my my opinion. It's not a criticism, okay. It's a statement. Okay. Number two is, these are peripheral
2 3 4 5	most nerves can be seen by any stain. Do you agree with that? A. Yeah. Most nerves are visible without staining. You can see that.	2 3 4 5	A. This is my my opinion. It's not a criticism, okay. It's a statement. Okay. Number two is, these are peripheral nerve. Peripheral nerve is able to grow. All right?
2 3 4 5	most nerves can be seen by any stain. Do you agree with that? A. Yeah. Most nerves are visible without staining. You can see that. Q. And then he goes on to say that, "This nerve is present within a space between filaments, or a	2 3 4 5	A. This is my my opinion. It's not a criticism, okay. It's a statement. Okay. Number two is, these are peripheral nerve. Peripheral nerve is able to grow. All right? Dr. Iakovlev also made a similar statement. This is correct. Okay. Then if these tissue can grow just like
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- 1 A. Because you have vessel, you have healthy
- ² fibroblasts. You see the vessels there? And although
- 3 he did not label that, but in other pictures, you -- you
- 4 will see vessels.
- 5 Q. Where do you see vessels at?
- 6 A. Vessels are everywhere. Many, one, two,
- 7 three, four and small -- these areas. Okay. All these
- 8 little bit of space with linings, they are all vessels.
- ⁹ These microvessels everywhere, okay, number one.
- Number two, you see nerve, as he labeled
- 11 it very clearly. In this field, you have several nerve
- 12 fibers clearly seen there. Okay. And the nerve grow do
- 13 not grow into pure scar. Nerve grow, you need a
- 14 vascular supply or nutrition to keep alive. Okay. So
- 15 these are -- that's the reason these are fibroconnective
- 16 tissue. It's integrated tissue.
- Q. Okay. So number one, you're saying that
- 18 because nerves grow and are growing into the scar --
- 19 A. I didn't say --
- MR. VOUDOURIS: Objection.
- A. -- grow into the scar. That -- you are
- 22 saying --
- Q. (BY MR. THORNBURGH) Growing into the
- 24 fibroconnective tissue?
- MR. VOUDOURIS: Objection.

- 1 other side of the mesh pore.
 - Q. Do you think Dr. Iakovlev made that term up?

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Page 189

- 3 A. I -- I don't see anyone else use this term so
- 4 far based on my understanding.
- Q. You haven't seen Ethicon's internal documents
- 6 dating back as far as 1990s discussing bridging
- 7 fibrosis?

12

- 8 MR. VOUDOURIS: Objection; form.
- 9 A. Okay. Then --
- 10 Q. (BY MR. THORNBURGH) Is that correct, you
- 11 haven't seen those documents?
 - A. I did not remember, you know, these terms came
- 13 from those. But anyway --
- MR. VOUDOURIS: Hold on, there's not a
- 15 question pending.
- 16 THE WITNESS: Okay.
- Q. (BY MR. THORNBURGH) So the one -- so we
- talked about you don't believe bridging fibrosis.
- 19 That's a term that was made up.
- MR. VOUDOURIS: Objection.
- Q. (BY MR. THORNBURGH) And the next is -- well,
- 22 let me ask you this -- let me withdraw.
- You see the inflammation there,
- 24 identified?
- A. Yes. We have inflammation, yes.

- 1 A. Yeah. Together with the fibroconnective
- 2 tissue, nerve can grow as part of the integrated tissue.
- 3 Q. (BY MR. THORNBURGH) Okay. So that's assuming
- 4 that these nerves actually grew and didn't get
- 5 entrapped, right?
- 6 MR. VOUDOURIS: I'll object; form,
- 7 foundation.
- 8 A. That's why we're saying -- peripheral nerve
- 9 can grow is a demonstrated fact. Everybody knows, okay?
- 10 That's well-known medical knowledge, all right? So they
- 11 can grow. Because after injury -- injury mean with --
- 12 the surgery itself is an injury, right? You've cut the
- 13 tissue, you implant the mesh, that's injury. Then you
- 14 create a space, mesh has a space.
- And then these tissues will fill the
- 16 space, become integrated tissue, and become mesh and
- 17 tissue complex, which is a normal function for -- or the
- 18 biological basis for the mesh to support or to correct
- 19 the symptoms in a clinical side.
- Q. (BY MR. THORNBURGH) So you -- let me ask this
- 21 question: Do you at least agree that there's
- 22 fibroconnective tissue bridging from pore to pore?
- A. No. I didn't say bridging because bridging
- 24 fibrosis is his term, all right? That's Dr. Iakovlev's
- 25 term, bridging fibrosis, basically from one side to the

- Q. Okay. What level of inflammation do you see
- 2 in this slide?
- A. It's where -- it's focal area -- first of all,
- 4 this is only focal area --
- 5 O. Uh-huh.
- 6 A. -- of the microscopic picture. This amount of
- 7 inflammation most likely will be rendered as mild
- 8 inflammation.
- 9 Q. And that's because -- I think, if I
- 10 understand --
- 11 A. Because --
- MR. VOUDOURIS: Hold on. Don't talk over
- 13 each other, Doctor. Let him get his question out.
- Q. (BY MR. THORNBURGH) If I understand the way
- 15 that you look at these and the way you define, you know,
- 16 put these into categories, you would call this sparse,
- 17 scattered inflammatory infiltrates --
- 18 A. Yes.
- 19 Q. -- is that right?
- And when you say "focal area," are you
- 21 talking about a zoomed-in area? Is that what you mean
- 22 by that or --
- A. That's the area in this picture he use
- 24 arrow with inflammation. See that?
- 25 Q. Alloy?

Case 2:12-md-02327 Document 2834-4 Wenx Filed 09/19/16 Page 50 of 73 PageID #: 98327 in Zheng, M.B. Page 190 Page 192 1 MR. VOUDOURIS: Arrow. 1 moderate. When I asked you --2 A. No. A. Arrow. 3 Q. (BY MR. THORNBURGH) Arrow. Okay. 3 Q. -- to write "moderate" --4 So the arrow -- so he's pointing to an A. No. When I say moderate -- if I say -- if I 5 arrow that shows inflammation, but you don't see many areas like this, all right, in the same 6 believe -- you believe that the location of specimens, then I will say this is moderate. that -- strike that. Q. But you testified a moment ago -- you circled You believe that the level of inflammation the page, and you said, "If we look at this area alone 9 at the location of that arrow is mild? where the circle is around the fiber, that would be 10 A. I -- I say overall with this area you see moderate." 11 adjacent, except this area, the remaining area has 11 A. No. I said if I see this alone together with 12 basically no inflammation. 12 other areas like this, then will be moderate. 13 Q. Okay. 13 Q. If we look at -- if we look at the -- just the 14 A. Therefore, overall, this is mild inflammation. 14 area --15 15 Q. Okay. So let's -- let's try to figure this A. Right. 16 out. Can you take this pen. So if we -- when you talk 16 Q. -- around the fiber, you agree with me that 17 about looking at the entire area and grading it based on that's moderate inflammation, right, around the fiber? 18 the entire area, that would include the area adjacent MR. VOUDOURIS: Objection; form. 19 and outside or away from the fibers, right? 19 A. You are separating the whole situation, A. Yes. I will estimate immediate close to the pointing to a very -- just like we -- we are talking 21 mesh fiber spaces, as well as a few millimeter away from about a forest, and you're pointing to a single leaf and 22 the mesh fiber spaces or adjacent to fibroconnective 22 what this leaf represents. That question becomes very difficult to answer. 24 Q. Well, what's the level of inflammation around 24 Mild, moderate, and severe just follow, 25 the mesh fibers at the location of the arrow? ²⁵ you can see. We discussed that already. I follow

- 1 A. This area [indicating].
- Q. So what's -- what's the grading that you would
- 3 give that area for -- of inflammation?
- A. If -- if this area alone almost everywhere
- 5 like this, then this will be moderate.
- Q. Okay. So circle the area that you see as 7 moderate.
- 8 A. [Witness complies.]
- 9 Q. Okay. Can you just write -- draw an arrow to
- 10 the circle that you made and write "moderate" for me so
- 11 that we can see that on the exhibit.
- 12 A. [Witness complies.]
- 13 Remember, if I say similar area have to be
- 14 found in the different places rather than just only one
- 15 single focus --
- 16 Q. I hear you. Let's -- let's --
- 17 A. -- okay? So if you have more area like this,
- 18 then I'm going to render as a moderate.
- 19 Q. So just --
- 20 A. If this is alone, this will be mild.
- 21 Therefore, if you want me to say this picture alone
- 22 represent what, this going to be mild.
- Q. Well, no. Hold on. 23
- 24 A. Right?
- 25 Q. You just indicated earlier that it was

- Page 193
- 1 Dr. Hill's paper. It's very clear there. And also, we
- 2 have other examples for mild and moderate area in my
- 3 report too.
- Q. (BY MR. THORNBURGH) Okay.
- A. So that's the reason it's difficult to -- for
- 6 you -- you want me circle this area, say it's mild,
- 7 moderate, or severe.
- Q. The area that you circled, if -- if the entire
- area, the entire slide, looked like the area that you
- circled next to the mesh fibers, that would be graded by
- 11 you as moderate, right?
- 12 A. Yeah, I can say that.
- 13 Q. Because -- because there are a -- if we look
- at the definition from -- from Dr. Hall -- or Hill, from
- Exhibit 8, there's moderate chronic inflammatory
- infiltrates in areas of giant cell reaction around --
- 17 around the mesh fibers on that image?
- 18 MR. VOUDOURIS: Objection.
- 19 A. That's right. But still, you need amount.
- 20 It's not like without amount you can just say in that
- way. I even cannot tell here there is giant cell or not
- 22 because this micrograph is -- does not illustrate giant
- 23 cell there.
- 24 Q. (BY MR. THORNBURGH) All right. So if we look
- 25 at -- okay. And so you don't believe that this is

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	Page 194		Page 196
1	fibroconnective tissue that in between the pores?	1	But we can confirm, you know, using microscope.
2	_	2	Q. (BY MR. THORNBURGH) So you'd need you
3		3	
4		4	A. Yeah.
5		5	Q. Is that true for strike that.
6		6	Higher power power would allow you to
7		7	give a more reliable
8		8	A. Estimation.
9		9	Q estimation?
10		10	A. Correct.
11		11	
12			Q. All right. Okay. Go to paragraph 2.
١	The state of the s	12	A. Paragraph 2. B?
13	6	13	Q. On Page 21 of Exhibit 2.
14	1	14	A. 21, okay.
15		15	Q. And this is where you discuss the erosion?
	to	16	A. Yes.
17	8	17	Q. Okay. And you say that "Dr. Iakovlev notes
18		18	the mucosal erosion in Ms. Corbet's explanted mesh by
19	again. All right.	19	showing interrupted squamous mucosa and granulation
20	MR. SNOWDEN: He just gave it about five	20	tissue and mixed inflammation" [as read].
21	minutes ago.	21	And then you cite to CK his Figure
22	Q. (BY MR. THORNBURGH) All right. So where do	22	CK1c, right?
23	you see on exhibit on Figure K CK5a what you	23	A. Correct.
24	described as vessels?	24	Q. And you you essentially say that while
25	A. Do you want me to label that?	25	there is a clinical finding of erosion in other
	Page 195		Page 197
1		1	words, Dr. Smith found an erosion upon examination
2			you don't believe that there is an erosion identified or
3	_		observable on CK1c of his report, right?
1 4	•	4	MR. VOUDOURIS: Objection; form.
-	In this lower power, you easily can	5	A. Yeah.
	identify many vessels, V. If I magnify it to the higher	6	MR. VOUDOURIS: Go ahead.
	power, we can see much better vessels. It's difficult		
	for you to understand probably for micro microscopic	7	A. Pathologically, this picture, his CK1a
8	1	8	picture, is very fragmented, okay? Do you see that?
9	C	9	Q. (BY MR. THORNBURGH) And we're talking about
10		10	CK1c, right?
11		11	A. 1a. 1a.
	Okay.	12	Q. 1a and c? Okay. Let's look a and c.
13	2 . — - y - a - c - c - c - c - c - c - c - c - c	13	A. I would say 1a, b, and c, right?
14	81.	14	Q. Okay. So if you go to Page 99 of his expert
15	· · · · · · · · · · · · · · · · · · ·	15	report, right?
16	4 . (= 1 = 1	16	A. Right.
17	record, I'll just go ahead and mark 1, 2, and 3. So	17	Q. He says "Mucosal erosion site." And he uses
18	1 1, 2, 3. I've marked on Page 108 the fibers and	18	H&E staining?
19	asked if you see any vessels within or between fiber 1,	19	A. Right. And then, based on these pictures, no
20	2, and 3.	20	pathologist can say this is the erosive site because
21	(Witness reviewed document.)	21	these tissues are fragmented.
22	MR. VOUDOURIS: Objection; form.	22	Q. What do you mean by that?
		1	

23

25

A. It is very likely -- it's lower power again,

24 okay. It's very likely just underneath of this arrow

25 that's a vessel. Even red blood cells inside. Okay.

A. You see multiple pieces. They are not intact

Q. All right. So your -- it's your opinion that

24 tissue. Right? Do you understand?

- 1 no -- no pathologist could find an erosion on this --
- 2 this specimen because they're fragmented?
- A. Yeah. Because nobody can say, based on these
- 4 findings, that represent erosive site.
- 5 Q. What about on CK1c?
- 6 A. CK1c, we have squamous mucosa, right, and
- 7 underneath of the mucosa, we have, yes, mixed
- 8 inflammation. That, I agree. Lots of inflammation
- 9 there, okay? This area we can say is moderate. That's
- 10 fine. Okay. And then there is underneath another
- 11 picture showing like lamina propria or fibroconnective
- 12 tissue underneath. You see this?
- 13 Q. Okay.
- A. And then -- however, these three pictures do
- 15 not show any mesh fiber. Where is the mesh?
- Q. Okay. But you do see the -- the mucosa's
- 17 there, right?
- A. Mucosa is there.
- Q. And that -- that's what -- where the mesh
- 20 would have eroded through?
- MR. VOUDOURIS: Objection; form,
- 22 foundation.
- A. Mucosa is part of the vagina, and Dr. Smith
- 24 trim and excised a portion of the mesh, right? And if
- ²⁵ you want to demonstrate this is the erosive site, you

- Page 200
- 1 to higher magnification. Then we are able to tell.
- Q. So on Page 101, CK1c, you are agreeing that
- there is chronic inflammation observed there of a
 moderate level, but you just can't offer an opinion --
- 4 moderate level, but you just can't offer an opinion -
- 5 you can't state to a reasonable degree of medical or
- 6 scientific probability that this is the site of the
- 7 erosion?
- 8 A. Correct. Because if I were Dr. Iakovley, I
- 9 will take very low power to show the whole picture,
- 10 where is the mesh, where is the mucosa. Then, that's a
- 11 good demonstration. But he didn't. Why he didn't, you
- 2 can ask him.
- That's why I say there is no convincing
- evidence from pathological point of view there is
- 15 erosive site, but I did not disagree with Dr. Smith's
- 16 finding in the clinical side. It's different -- two
- 17 different issue.
- Q. Okay. If you go on to 3 -- paragraph 3 -- let
- 19 me as -- well, strike that.
- Before I go there, did you -- have you
- 21 asked to look at the microphotograph -- strike that.
- Have you asked to look at, or did you look
- 23 at, in rendering your opinions in this case the slides
- 24 that were evaluated by Dr. Iakovlev?
 - A. When I read these slides, I think before I

Page 199

- 1 have to show immediate adjacent to the mucosa you have
- 2 mesh. Then that means it's exposure. Do you
- 3 understand?
- 4 Q. (BY MR. THORNBURGH) I think I understand what
- 5 you're saying, but I thought you agreed, though, that at
- 6 the site of erosion, you would get a heightened level of
- 7 inflammatory response, right?
- 8 A. That's fine, yeah. Yes. Most of the case,
- 9 yes, they have enhanced level of inflammation.
- Q. And you'd agree that on CK1c, these slides
- 11 demonstrate an enhanced moderate inflammatory response?
- 12 A. Compared to the remaining specimen, yes, more
- 13 inflammation's found in this area.
- 14 Q. And are those -- do you see acute, or do you
- 15 see chronic inflammatory response?
- 16 A. We have both acute and chronic. That's
- 17 so-called a mix.
- Q. And how do you see acute?
- 19 A. Acute is neutrophil and chronic is
- 20 lymphocytes.
- Q. And how are those two things colored
- 22 differently on -- or stained differently on your -- on
- 23 that --
- A. Because in this level, you are not able to
- 25 tell. They all become black box. You have to magnify

1 read these slides, then Dr. Iakovlev already read. He

- 2 read first.
- 3 Q. Okay. But you didn't actually get a
- 4 slide -- the slides that Dr. Iakovlev had and looked at
- 5 those slides under a microscope; you're just looking at
- 6 his photomicrographs?
- MR. VOUDOURIS: No. Objection.
- 8 A. No.
- 9 MR. VOUDOURIS: He did look at the slides.
- 10 A. I did look at the slides. I did look at the
- 11 slides.
- Q. (BY MR. THORNBURGH) Okay. That's why -- I
- 13 just -- I'm trying to understand that.
- A. The slides are identical slides.
- Q. Okay. So did you try to find the slide that
- 6 we saw on CK1c and take a photomicrograph of it in a
- 17 larger or a lower magnification?
- MR. VOUDOURIS: Objection; compound.
- A. I see this inflammation, but the -- I think,
- 20 based on my memory, the mesh fiber is away from this
- 21 site. It's not really immediately adjacent to the
- 22 mucosa.
- 23 Q. (BY MR. THORNBURGH) Because earlier you
- 24 testified if you were Dr. Iakovley, you would look at
- 5 that slide and zoom out so that you could see where the

Case 2:12-md-02327 Document 2834-4 Filed 09/19/16 Page 53 of 73 PageID #: 98330 Wenxin Zheng, M.B. Page 202 Page 204 1 mesh fibers are, right? 1 You have -- a majority of them, they're mild; the focal 2 A. Yes. 2 area will be moderate. That's fine. 3 Q. Where -- which of those exhibits did you Q. Did you do --4 A. If -- if I believe this represents the erosive find -- I'm sorry. Let me ask a better question. 5 site or exposure site, I will take a lower power In those figures, did you find a focal picture, then have the high power picture to show. 6 area of moderate fibrosis in each one of those figures? Q. Despite that you had the same slides, you A. For instance, he labeled -- he -didn't do that in your -- you didn't take --Q. If could you identify the page number that 9 A. Because there is no evidence. you're on --10 10 Q. Okay. But you didn't -- you didn't A. Okay. That's page -- Page 104. All right? 11 demonstrate that in a photomicrograph attached to your And he labeled was a fibrous tissue, and in parentheses, "scar." Then again, he said, "Bridging or crossing a 12 expert report, right? 13 pore." 13 A. Because there is no evidence of erosive site 14 can be demonstrated from the slides. That's why --14 Actually, based on my understanding here, what's the reason I take a picture for that? 15 it is -- very focally, it's a moderate fibrosis. But 16 Q. It's a heightened, mixed inflammatory response in -- even if a moderate fibrosis you see immediate 17 mucosa. adjacent that there are multiple vessels. Then 18 underneath, you have loose connective tissue. A. I acknowledge that, that the --19 MR. VOUDOURIS: Objection. 19 Q. Okay. Can you circle for me the areas that 20 A. -- focal area has that. 20 you agree demonstrate focal moderate fibrosis? 21 Q. (BY MR. THORNBURGH) All right. 21 A. These are the area of focal moderate fibrosis 22 A. You understand, right? 22 [indicating]. 23 23 Q. Yeah. Your opinions in paragraph 3 --Q. And that's on Page 104, Figure CK2c, right? 24 A. Okay. 24 A. Yes. And you have vessels, vessels, vessels 25 MR. VOUDOURIS: We're on page ...? 25 [indicating]. Page 203 Page 205 MR. THORNBURGH: Page 21 still. 1 1 Q. Can you just -- if you go to 3a, CK3a? Q. (BY MR. THORNBURGH) You say "Dr. Iakovlev 2 2 A. Yeah. CK2a, 3a. Okay. 3 identifies diffuse scar tissue by showing multiple 3 MR. VOUDOURIS: Page 105. 4 histological pictures" [as read], and then you provide a 4 A. CK3a. Page 105. 5 list of different figures that are in his report. Then 5 Q. (BY MR. THORNBURGH) Page 105, yeah. 6 you opine that his interpretation is incorrect, and All right. Now, this says, "CK3a, tissue 7 you -- and you state that the basis for that is that his edema within mesh spaces, H&E, 20X objective, mesh 8 report clearly shows viable fibroblasts within the filaments filled with yellow in the labeled copy of the 9 collagen, right? 9 image" [as read]. 10 A. Correct. 10 In these fields, there are areas of 11 Q. And then you said that means the presence of fibrous tissue where collagen is separated by empty 12 mild to moderate degree of fibrosis? spaces. Do you see any -- do you disagree with that 13 MR. VOUDOURIS: Without mature --13 statement? 14 A. Correct. A. Yes. Because I still disagree mainly because 15 MR. VOUDOURIS: -- or pure scar tissue. 15 there is no way you can tell these are loose connective 16 Q. (BY MR. THORNBURGH) -- without mature or pure 16 tissue versus edema. 17 17 scar tissue. Q. And what was the basis for that opinion? 18 18 So is it -- let me just understand. If A. Because it's just a -- you have a little bit 19 I -- understand your opinion correctly, you agree that 19 of light space there. 20 there's a mild to moderate degree of fibrosis observed 20 Q. Because of the light space?

- 21 within CK2a, 2b, 2c, 3a, 3b, and 4?
- 22 A. In the different --
- 23 Q. You're just -- but you don't believe it's a
- 24 mature scar?
- A. Yeah. In here and there, it's a focal area. 25

- 21 A. Yeah.
- O. Because of the stain -- the color of the 22
- 23 stain?
- 24 A. Right. That's -- you have a whitish area.
- 25 You don't know they are loose connective tissue or

Page 206 Page 208 1 because of a watery kind of element there, so-called Q. -- fibrosis? A. I didn't in that. 2 edema. 3 Q. Okay. So do you agree that there's edema 3 O. What --4 identified in CK3a? A. I do not. 5 MR. VOUDOURIS: Objection. Q. It says that there are lymphocytes identified A. I cannot be sure this is edema. And he 6 within this image. Do you see the lymphocytes? 6 interprets as edema, but if it was my opinion, I don't A. Yes. Lymphocytes, I agree. 8 think I'm going to label this area represent edema. Q. Now, and what is a lymphocyte an indication of Q. (BY MR. THORNBURGH) If you look at the image in terms of the grading of fibrosis? 9 10 on the left on Page 105, CK3a, the very bottom --A. It's -- it's a main component of the 11 A. Yes. inflammation. So the amount of lymphocytes, people use 12 Q. -- underneath -- I'll point to you right here. that to judge the grade of the inflammation. 13 This area here [indicating]? 13 Q. And the presence of lymphocytes makes the 14 A. Yes. 14 severity of the inflammation greater? 15 MR. VOUDOURIS: Objection; form. 15 MR. VOUDOURIS: Which area are you 16 A. No. Lymphocytes almost -- is very commonly pointing to? 17 MR. THORNBURGH: On the very bottom -- we present adjacent to these mesh fibers. That's a part of can -- we can circle it. the normal tissue response. 18 Q. (BY MR. THORNBURGH) Normal tissue response 19 Q. (BY MR. THORNBURGH) We'll circle on Page 105. 19 A. [Witness complies.] 20 to --20 21 Q. What do you see in that image? 21 A. To implants. A. That's still fibroconnective tissue with mild Q. -- foreign body? 22 22 23 degree of inflammation. 23 A. To foreign body implants. Q. You called that mild degree? Q. Did you see, either in the slides that are 25 contained within Dr. Iakovlev's report or within your 25 A. Yes. Page 207 Page 209 1 Q. And all the -- all the little purple dots, 1 own report, any evidence of nerves with -- in between 2 pores? what are those? 3 3 MR. VOUDOURIS: Objection; form. MR. VOUDOURIS: Objection. Q. (BY MR. THORNBURGH) Or nerve distortion? 4 Go ahead. 4 5 A. Purple dots? You mean black one here 5 MR. VOUDOURIS: Objection; form. 6 [indicating]? A. I did not see any nerve distortion, number 7 Q. (BY MR. THORNBURGH) Black dots? one. Number two, I didn't observe focal area of nerve 8 A. Yeah. Black dots -fibers adjacent to the mesh fiber spaces. 9 9 Q. (BY MR. THORNBURGH) And when I say Q. Look purple. 10 "distorted" -- "distorted nerves," what's -- what does a A. -- can be inflammatory cell. Also can be 11 distorted nerve look like? 11 fibroblast, nuclei of the fibroblasts. 12 12 Q. Within that circle area, you're saying that's MR. VOUDOURIS: Objection. 13 Q. (BY MR. THORNBURGH) Does it bend? 13 sparse, separated inflammatory cells? 14 A. Yes. 14 MR. VOUDOURIS: Objection; form. 15 15 A. Based on my past experience practicing Q. If you turn the page to CK4. 16 pathology over 20 years, all right, I see normal nerve A. CK4. 17 endings or fibers in the vaginal tissue. They all look Q. It's on Page 107. 18 similar like this; therefore, there is no evidence there 19 Q. Okay. So you, again, disagree that this image is an abnormal -- abnormality. demonstrates fibrosis? 20 When you say "distortion," basically, it's one of the form. I -- I don't think any pathology --21 A. We have certain degree of fibrosis, that's you know, a typical pathology textbook will describe as 22 true. Probably is mild. But this is too -- magnify too a distortion. ²³ high. You need an overall picture. 23 24 Q. In this picture, do you see moderate --Q. (BY MR. THORNBURGH) Let's look -- if you look 25 at Page 109, CK5b, Dr. Iakovlev's report. And do you 25 A. I don't --

	WellXIII Zi		
	Page 210		Page 212
	see the	1	A. Yes.
2	A. The nerve.	2	Q 20 times, 20X?
3	Q nerve that's identified?	3	A. Right.
4	A. Yes.	4	Q. And you include let me ask you this
5	Q. You agree that's a nerve, number one, right?	5	question: How many microns, i you know, from the mesh
6	A. Oh, yeah, sure.		fiber is that strike strike it. Let me ask a
7	Q. And is that within the fibroconnective tissue	7	better question.
8	near the fibers?	8	You have M there. You see the M?
9	MR. VOUDOURIS: Objection	9	A. Right. M is mesh fiber spaces, yes.
10	A. Near the	10	Q. So you have you say mesh M labels the
11	MR. VOUDOURIS: form.	11	mesh spaces?
12	A filaments.	12	A. Yes.
13	Q. (BY MR. THORNBURGH) Near the filaments?	13	Q. Okay. So because that looks like a mesh
14	A. Yes.	14	fiber to me, not a space.
15	Q. And and you don't believe that that nerve	15	A. Because it's a space because the real mesh
16	is distorted in any way?	16	is sloughed after tissue processing.
17	A. No; not at all. Because it's a common	17	Q. Okay. So that's where the mesh
18	finding, this shape, because depending on the cut.	18	A. Located originally
19	Q. Depend	19	Q fibers were located?
20	A. The tissue.	20	A in vivo.
21	Q depending on the cut of the	21	Q. That's where the mesh fibers were located in
22	A. Of the tissue.	22	vivo, right?
23	Q tissue?	23	A. Correct.
24	A. Yeah.	24	Q. So that's not really that's not a pore
25	Q. Okay. Let's look at some of your slides real		there; that's actually the mesh fiber?
	Q. Shaji Zevs ison ur some si your shaes iour		,,,,,
	Page 211		Page 213
1	Page 211 quick. Let's go to Page 12.	1	Page 213 A. Right. It's a it's a cluster of the mesh.
1 2	_		
	quick. Let's go to Page 12.		A. Right. It's a it's a cluster of the mesh.
2	quick. Let's go to Page 12. A. From my own report?	2 3	A. Right. It's a it's a cluster of the mesh. It is in knots basically.
2 3	quick. Let's go to Page 12. A. From my own report? Q. Yeah. Yeah, your report, Exhibit 2, Page 12.	2 3 4	A. Right. It's a it's a cluster of the mesh.It is in knots basically.Q. Okay. And then you have this image
2 3 4 5	quick. Let's go to Page 12. A. From my own report? Q. Yeah. Yeah, your report, Exhibit 2, Page 12. MR. VOUDOURIS: Exhibit 2?	2 3 4	 A. Right. It's a it's a cluster of the mesh. It is in knots basically. Q. Okay. And then you have this image includes a considerable amount of tissue without mesh in
2 3 4 5	quick. Let's go to Page 12. A. From my own report? Q. Yeah. Yeah, your report, Exhibit 2, Page 12. MR. VOUDOURIS: Exhibit 2? MR. THORNBURGH: I think it's Exhibit 2,	2 3 4 5	 A. Right. It's a it's a cluster of the mesh. It is in knots basically. Q. Okay. And then you have this image includes a considerable amount of tissue without mesh in it, right?
2 3 4 5 6	quick. Let's go to Page 12. A. From my own report? Q. Yeah. Yeah, your report, Exhibit 2, Page 12. MR. VOUDOURIS: Exhibit 2? MR. THORNBURGH: I think it's Exhibit 2, right?	2 3 4 5 6 7	 A. Right. It's a it's a cluster of the mesh. It is in knots basically. Q. Okay. And then you have this image includes a considerable amount of tissue without mesh in it, right? A. Correct. That's adjacent
2 3 4 5 6 7	quick. Let's go to Page 12. A. From my own report? Q. Yeah. Yeah, your report, Exhibit 2, Page 12. MR. VOUDOURIS: Exhibit 2? MR. THORNBURGH: I think it's Exhibit 2, right? MR. VOUDOURIS: Oh, I thought you were	2 3 4 5 6 7	 A. Right. It's a it's a cluster of the mesh. It is in knots basically. Q. Okay. And then you have this image includes a considerable amount of tissue without mesh in it, right? A. Correct. That's adjacent so-called adjacent fibroconnective tissue excised by
2 3 4 5 6 7 8	quick. Let's go to Page 12. A. From my own report? Q. Yeah. Yeah, your report, Exhibit 2, Page 12. MR. VOUDOURIS: Exhibit 2? MR. THORNBURGH: I think it's Exhibit 2, right? MR. VOUDOURIS: Oh, I thought you were referring that it says on Page 12, Exhibit 2.	2 3 4 5 6 7 8	 A. Right. It's a it's a cluster of the mesh. It is in knots basically. Q. Okay. And then you have this image includes a considerable amount of tissue without mesh in it, right? A. Correct. That's adjacent so-called adjacent fibroconnective tissue excised by Dr. Smith.
2 3 4 5 6 7 8 9	quick. Let's go to Page 12. A. From my own report? Q. Yeah. Yeah, your report, Exhibit 2, Page 12. MR. VOUDOURIS: Exhibit 2? MR. THORNBURGH: I think it's Exhibit 2, right? MR. VOUDOURIS: Oh, I thought you were referring that it says on Page 12, Exhibit 2. MR. THORNBURGH: No, no.	2 3 4 5 6 7 8	A. Right. It's a it's a cluster of the mesh. It is in knots basically. Q. Okay. And then you have this image includes a considerable amount of tissue without mesh in it, right? A. Correct. That's adjacent so-called adjacent fibroconnective tissue excised by Dr. Smith. Q. Okay. Do you know what the distance in
2 3 4 5 6 7 8 9	quick. Let's go to Page 12. A. From my own report? Q. Yeah. Yeah, your report, Exhibit 2, Page 12. MR. VOUDOURIS: Exhibit 2? MR. THORNBURGH: I think it's Exhibit 2, right? MR. VOUDOURIS: Oh, I thought you were referring that it says on Page 12, Exhibit 2. MR. THORNBURGH: No, no. MR. VOUDOURIS: I know what you're saying.	2 3 4 5 6 7 8 9	A. Right. It's a it's a cluster of the mesh. It is in knots basically. Q. Okay. And then you have this image includes a considerable amount of tissue without mesh in it, right? A. Correct. That's adjacent so-called adjacent fibroconnective tissue excised by Dr. Smith. Q. Okay. Do you know what the distance in approximately, in microns, is from the
2 3 4 5 6 7 8 9 10	quick. Let's go to Page 12. A. From my own report? Q. Yeah. Yeah, your report, Exhibit 2, Page 12. MR. VOUDOURIS: Exhibit 2? MR. THORNBURGH: I think it's Exhibit 2, right? MR. VOUDOURIS: Oh, I thought you were referring that it says on Page 12, Exhibit 2. MR. THORNBURGH: No, no. MR. VOUDOURIS: I know what you're saying. I apologize.	2 3 4 5 6 7 8 9 10	A. Right. It's a it's a cluster of the mesh. It is in knots basically. Q. Okay. And then you have this image includes a considerable amount of tissue without mesh in it, right? A. Correct. That's adjacent so-called adjacent fibroconnective tissue excised by Dr. Smith. Q. Okay. Do you know what the distance in approximately, in microns, is from the A. This is not microns. Several millimeter.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	quick. Let's go to Page 12. A. From my own report? Q. Yeah. Yeah, your report, Exhibit 2, Page 12. MR. VOUDOURIS: Exhibit 2? MR. THORNBURGH: I think it's Exhibit 2, right? MR. VOUDOURIS: Oh, I thought you were referring that it says on Page 12, Exhibit 2. MR. THORNBURGH: No, no. MR. VOUDOURIS: I know what you're saying. I apologize. THE WITNESS: My report, Exhibit 4. MR. VOUDOURIS: Your report is Exhibit THE WITNESS: 4. MR. THORNBURGH: Oh, Exhibit 4? MR. VOUDOURIS: Yes. Exhibit 2 is the hard drive MR. THORNBURGH: That's right. MR. VOUDOURIS: I'm sorry is the disc, yeah, portable disc. Q. (BY MR. THORNBURGH) So Exhibit 4, your expert report, go to Figure 3.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Right. It's a it's a cluster of the mesh. It is in knots basically. Q. Okay. And then you have this image includes a considerable amount of tissue without mesh in it, right? A. Correct. That's adjacent so-called adjacent fibroconnective tissue excised by Dr. Smith. Q. Okay. Do you know what the distance in approximately, in microns, is from the A. This is not microns. Several millimeter. Q. Several millimeters? A. Okay. Because the lower power 2X lower power, 20X lower power. The whole field is about 1.1 centimeter. So this is cut like from mesh to this area at least a 5 millimeter [indicating]. Q. Okay. So it's at least 5 millimeters of tissue that significant a vast majority of the image doesn't show tissue that had mesh in it, right? A. Correct. Q. And when you look at a slide, you look at it at a low a low power, like 20X, or even lower, right?

1 want to show.

- Q. Okay. And so when you graded this sample --
- 3 or this slide, for inflammation, you included several
- 4 millimeters of tissue that wasn't even near the mesh,
- 5 right?
- 6 A. I --
- 7 MR. VOUDOURIS: Objection; form.
- 8 A. I included both immediate adjacent to the mesh
- 9 and the tissue away from the mesh. So this picture, I
- 10 say, barely shows any inflammation in this area, in the
- 11 several millimeter tissue -- several millimeter away
- 12 from the mesh fiber.
- Q. (BY MR. THORNBURGH) So the area further --
- 14 furthest away -- so on exhibit -- Page 12, Figure 3, you
- 15 say barely shows any inflammation in these areas, and
- 16 that's the area that's furthest away from the mesh
- 17 fibers, right?
- 18 A. Correct.
- Q. And as you get closer and closer to the mesh
- 20 fibers, you get a greater and greater inflammatory
- 21 response?
- A. It's not greater and greater. Still minimal
- 23 is there. You can see still is a bluish area adjacent
- to the mesh fiber. That's minimal. It's mild.
- 25 Q. It's --

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 went off the record, we were looking at Exhibit 4, your
- 2 expert report and specifically Figure 3, right?
- 3 A. Yes.
- Q. Which is 20X power, low power, right?
- 5 A. Yes.
- 6 Q. And I'm still a little bit confused on how
- ⁷ you are -- how you are grading this slide. I think --
- 8 correct me if I'm wrong, but you look at the entire
- 9 slide at low power, which includes tissue that is
- 10 several millimeters away from the mesh fibers, and you
- 11 calculate, by looking at -- looking at the entire slide,
- the number of inflammatory cells within the entire slide
- 3 to reach your final grading of that slide. Is that
- 14 accurate?
- 5 A. I think this picture I want to show you
- overall situation in the lower power, including mesh and
- 17 tissue immediate adjacent to mesh and tissue several
- 18 millimeter away from the mesh.
- So I try to show you the overall situation
- of the specimen. This is a good way to show overall
- 21 picture of the specimen rather than just magnify in a
- 22 very focal area to show some very dense inflammation
- 23 area.
- So therefore, I think this -- this is the
- 25 message I want to convey. All right? Yes, I based

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- 1 A. Yes.
- 2 Q. -- minimum when you take the entire slide into
- 3 consideration?
- 4 A. Correct.
- 5 Q. Including slide -- including tissues that are
- 6 several millimeters away from the actual mesh?
- 7 A. No. I -- I clearly separate them. If several
- 8 millimeter away from the mesh, basically no
- 9 inflammation. And then mild -- majority of them, mild
- 10 inflammation is present. Mostly immediate adjacent to
- 11 the mesh fiber. It's clear, right?
- 12 Q. Well, I don't know about that.
- 13 A. Okay.
- MR. VOUDOURIS: Objection; move to strike.
- Can we go off the --
- Q. (BY MR. THORNBURGH) But that's what --
- MR. VOUDOURIS: Can we go off the record
- 18 for one second?
- 19 MR. THORNBURGH: Yeah.
- THE VIDEOGRAPHER: We're off the record at
- 21 3:46 p.m.
- 22 (Break taken.)
- THE VIDEOGRAPHER: We're back on record at
- 24 3:58 p.m., beginning tape 4.
- Q. (BY MR. THORNBURGH) Okay. Doctor, before we

- 1 on -- when I grade, I separate them, you know,
- 2 inflammation amount immediate adjacent to the mesh in

- ³ which condition, and then tissue several millimeter away
- 4 from the mesh in what kind of condition.
- 5 Q. Okay. And the reason I ask this question is
- 6 because all of the images or figures that you have in
- ⁷ your report are low power. The greatest power appears
- 8 to be 40 power, 40X, right?
- 9 A. Yeah, because 40X is the maximum routinely
- used by pathologist. Pathologist do not routinely use
- 11 oil lens. It's -- which is 100X. That means magnified 12 to 1,000.
- THE REPORTER: To one what?
- THE WITNESS: 1,000 because --
- MR. VOUDOURIS: 1,000.
- 16 THE WITNESS: 1,000.
- Q. (BY MR. THORNBURGH) And -- and if I
- 18 understand it correctly, that's how you -- you grade
- based on low magnification and come to a conclusion
- 0 based on the morphological features of the entire slide?
- A. That's not true because lower power is showing
- 22 you better overall picture. And when I'm grading, I
- always turn on the higher power to confirm they are
- 4 actually inflammatory cells.
 - Q. Okay. And by higher power, you mean 40X?

- 1 A. Yeah. Higher power is -- highest is 40X.
- 2 Q. That's the highest you'll go?
- 3 MR. VOUDOURIS: Objection.
- 4 A. 40X means -- is 40 -- it's 400 basically.
- 5 Because when we say 40X, we have two lenses close to the
- 6 slide, and the other lens is close to the eye. Close to
- 7 the eye, we always -- that's a 10X. You understand,
- 8 right?
- 9 Q. (BY MR. THORNBURGH) I understand. If you
- 10 look again just briefly at Exhibit 8 and go to Page 594,
- 11 which is the Hill article.
- 12 A. Right.
- Q. And you see the Figure 1 where they show
- 14 examples of how they grade?
- 15 A. Yes.
- Q. And they show examples of the -- of how they
- 17 graded certain slides?
- 18 A. Yes.
- Q. You would agree with me that that is -- that
- 20 the researchers in the Hill article are looking at those
- 21 samples greater than 40X?
- MR. VOUDOURIS: Objection.
- Q. (BY MR. THORNBURGH) Let me ask it a different
- 24 way. You'd agree that, number one, it's a greater --
- 25 it's greater power than 20X?

- 1 Q. Okay.
 - A. And then here, most likely, is a 40X.
 - Q. Okay. So you believe, based on your --
 - 4 A. Right.
 - 5 Q. -- knowledge, training, and experience that --

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- A. Right.
- 7 Q. -- Figure 1 --
- 8 A. It's like a 40X. Then the (b) specimen
- 9 probably about 100X. And then (c) specimen is also
- 10 100X.
- Q. Okay. What about the (d) specimen?
- 12 A. (D) probably is, maybe, similar or even
- 13 higher.
- Q. 100X or greater?
- A. 200X. And then (e) probably is lower,
- 16 possibly is a 40X.
- 17 O. (F)?
- A. (F) is kind of similar to the (b) and (c).
- 19 All right. That's based on my best judgment.
- Q. And do you believe it was appropriate or
- 21 inappropriate for the researchers in Hill to, for
- 22 example, in Figure 1c, use 100X magnification?
- MR. VOUDOURIS: Object -- objection; form,
- 24 foundation.
- A. That's perfectly appropriate because the

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- 1 MR. VOUDOURIS: Objection.
- 2 Q. (BY MR. THORNBURGH) Right?
- 3 A. Yes, greater than 20X.
- 4 Q. And would you agree it's greater than 40X?
- 5 MR. VOUDOURIS: Objection.
- 6 A. I'm not sure, because what did they say?
- 7 What's the magnification here? They did not -- in the
- 8 Figure 11, they did not specify. Did you see any
- 9 specification for the magnification?
- Q. (BY MR. THORNBURGH) No. I'm just asking
- 11 based on your knowledge, training, and experience what
- 12 it looked like to you.
- A. And based on my understanding, this one looks
- 14 like -- yes, a 4X. That means -- my -- this picture is
- 15 a 2X, 20X total. This one --
- Q. This -- when you say "this picture," you're
- 17 talking about Page --
- 18 A. My picture --
- 19 Q. -- 12?
- 20 A. -- 12, is --
- 21 Q. Figure 3?
- A. Yeah. Figure 3 total is a 20X.
- 23 Q. Okay.
- A. We are now -- all use a total magnification,
- 25 20X.

- 1 reason they want to show is to show example of the
- 2 degree of inflammation and the degree of fibrosis. So
- 3 therefore, depending -- depending on the purpose, then
- 4 use different magnification.
- 5 Q. (BY MR. THORNBURGH) Okay. And if you look at
- 6 Figure 4 on Page 13 of your expert report, you say,
- 7 "mesh with integrative fibroconnective tissue showing
- 8 mild degree of chronic inflammation" [as read], right?
- 9 A. Yes. Right. Then this time --
 - MR. VOUDOURIS: There's no question
- 11 pending. He just asked you if that's what you said.
- 12 Q. (BY MR. THORNBURGH) And then you have arrows
- 13 where you say, "Mild degree of chronic inflammation seen
- 14 in areas immediately adjacent to mesh filaments" [as
- 15 read], right?

- 16 A. Correct.
- 17 Q. And -- and this is at 40X?
- 18 A. Correct.
- 19 Q. And did you grade the degree of scar --
- 20 or fibroconnective tissue? You say mild inflammation,
- 21 but I don't see a grading for the fibroconnective --
- 22 what you call fibroconnective tissue.
- A. Fibroconnective tissue. I think I overall
- 24 mentioned we have mild degree of fibrosis.
- Q. When you say "overall," what do you mean?

Case 2:12-md-02327 Document 2834-4 Filed 09/19/16 Page 58 of 73 PageID #: 98335 Wenxin Zheng, M.B. Page 222 Page 224 1 A. That means this entire specimen. 1 together. 2 O. So --2 So in between those two -- those pores 3 A. And then --3 closest to the fiber, it's your opinion that to a Q. So -- so when you look at the specimen, you 4 reasonable degree of medical probability that the degree of fibrosis between those pores is moderate? 5 grade it as overall mild degree of inflammation, which 6 takes into account the tissue adjacent and away from the A. That's fine. 7 mesh filaments, right? Q. Would you agree that the severity of fibrosis A. Correct. is greater closest to the mesh filaments, mesh fibers? Q. What about the degree of fibrosis closest to MR. VOUDOURIS: Objection; form, 9 10 the mesh filaments, what is that level? 10 foundation. 11 MR. VOUDOURIS: Objection; form. 11 A. In general, yes. That's because that's the 12 A. Based on this picture, like on Page 13, my way tissue responds to mesh filaments. That's true. 12 13 Q. (BY MR. THORNBURGH) So that's something that 13 report, Figure 4, this is still mild degree. 14 Q. (BY MR. THORNBURGH) Okay. So let's make sure 14 would be common, right? 15 that the record reflects -- if you circle this area over 15 A. It's quite common. 16 here --16 Q. And expected? 17 17 A. Right. MR. VOUDOURIS: Objection. 18 Q. So go ahead and circle that. That's what you 18 A. It's expected. 19 call mild fibrosis, right? 19 Q. (BY MR. THORNBURGH) If you go to Figure 5, A. This one even no fibrosis this area 20 here you say, "There are occasional foci of moderate 20 21 [indicating]. And this area is mild, okay [indicating]? degree of chronic inflammation found in the specimen" Q. Well, let's go ahead and circle right here. [as read], right? 22 22 23 A. Correct. 23 What level of fibrosis do you see between those two 24 fibers? It's clearly greater than the two that you just Q. And you have arrows pointing to the moderate 25 degree of inflammation? 25 circled, right? Page 223 Page 225 MR. VOUDOURIS: Objection; form. A. Yes. 1 2 A. Yes. That's true, but this is so minor. It's Q. Is that chronic -- moderate degree of chronic 3 a very focal area. I mentioned that in my report, focal 3 inflammation, also? 4 area was moderate degree of fibrosis, so --A. That's -- I said moderate degree, right? Q. (BY MR. THORNBURGH) Go ahead and circle that That's occasional foci. 6 and identify that as you just did. If you could just Q. And is that common, to be -- a common finding 7 write it up here so I can read it later on. So moderate on your mesh fibers? 8 degree of focal fibrosis, right? MR. VOUDOURIS: Objection. 9 A. Yeah. 9 A. I should say majority of -- of the specimens 10 Q. And that's an area that's closest to and contains mild degree of inflammation based on my past 11 between two fibers, right? experience. And for this one, yes, we have focal area 12 A. That's very common too, yes. Okay. of moderate degree of inflammation. 13 Q. And same over here, go ahead and circle that 13 Q. (BY MR. THORNBURGH) And that's closer to the 14 area, the area between those two fibers. fiber, right? 15 A. [Witness complies.] 15 A. It's adjacent to the fiber. 16 Q. Okay. And you -- would you agree that that 16 Q. Immediately adjacent to the fiber? 17 17 also is moderate degree of fibrosis? MR. VOUDOURIS: Objection; form.

- 18 A. As I said, yes, I agree, but it's a very
- 19 common finding.
- 20 Q. Okay. Go ahead and identify that as moderate
- 21 degree of fibrosis.
- A. I already did. 22
- 23 Q. No. The second one we just talked about.
- 24 A. Merge together, right?
- 25 Q. Oh, so they're the same. You merge them

- 18 A. That depends how you define "immediate"
- because you still have some space between
- inflammation -- cluster of inflammatory cell and the
- 21
- Q. (BY MR. THORNBURGH) Okay. Then -- and then 22
- also on this image, Figure 5 on Page 14 of Exhibit 4, in
- your report, you say, "The mesh fiber spaces are
- visualized adjacent to the squamous mucosa" [as read].

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What's the significance of that finding?

- 2 A. That the squamous mucosa is the same, and then
- 3 underneath you see mesh fiber space. That's descriptive
- 4 of my finding.

1

- 5 Q. But then you -- but you say immediately after
- 6 that, "This is an indication -- a probable indication of
- 7 mesh site exposure" [as read], right?
- 8 A. Right. Then based on this finding, I think,
- 9 in -- in conjunction with a clinical finding of mesh
- 10 exposure, then possibly this picture will be much better
- 11 than the picture Dr. Iakovlev showed.
- Q. Okay. So can you go ahead and circle where
- 13 you see with -- or just write with this pen where you
- 14 see the squamous mucosa indicating probable mesh
- 15 exposure?
- 16 A. It's already --
- MR. VOUDOURIS: He already has an arrow
- 18 there.
- 19 A. -- in my Figure 11.
- 20 Q. (BY MR. THORNBURGH) I don't see it. I'm
- 21 sorry. Oh, down here. Well, it's just a -- can you
- 22 just write there "likely erosion" there?
- MR. VOUDOURIS: Objection.
- A. What do you mean likely --
- Q. (BY MR. THORNBURGH) That's a likely site of

- Q. Okay. So I'm going to try to accurately
- ² circle that where you just indicated, okay? Is that the

Page 228

Page 229

- 3 area of likely --
- 4 A. It is squamous.
- ⁵ Q. -- of the likely erosion?
- 6 A. No. I just --
 - MR. VOUDOURIS: Objection.
- 8 Q. (BY MR. THORNBURGH) -- or exposure?
- 9 A. No. You don't understand. This is the
- 10 squamous mucosa we found, okay? It's very tiny, all
- 11 right? It's -- it's better than the picture
- 12 Dr. Iakovlev showed because he showed a picture very
- 13 fragmented.
- And then I was looking very carefully
 - because I noticed that clinically there is exposure
- 16 site. So then underneath you see -- adjacent to this
- area, you see several mesh fiber spaces, right?
 - Q. (BY MR. THORNBURGH) Uh-huh.
- A. And then there is a distance from mesh fiber
- 20 spaces to this squamous mucosa is probably within a
- 21 millimeter of distance.
- 22 Q. I got it.
- A. Therefore, it's possible -- I didn't say it's
- definitive. It's possible this area represents exposure
- 25 site.

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- 1 erosion, right?
- 2 A. I--
- 3 MR. VOUDOURIS: Objection.
- 4 A. I say -- let me see. One is located...
- 5 (Witness reviewed document.)
- 6 A. "Indicating a probable mesh exposure site."
- 7 It's very clear there. Why you want a
- 8 separate --
- 9 Q. (BY MR. THORNBURGH) Because we've been doing
- 10 this game, so --
- 11 A. You can do by yourself because this is just
- 12 clearly there, then --
- 13 Q. I'll go ahead and do it for you.
- 14 A. Right.
- 15 Q. So -- so is it -- is it right --
- A. It's not for me. You -- because I already
- 17 indicated very clearly.
- 18 Q. I see. But I want to see --
- 19 A. Right.
- 20 Q. -- a precise location. So if I circle --
- 21 MR. VOUDOURIS: Objection.
- Q. (BY MR. THORNBURGH) -- this area, is that the
- 23 area that you see it, or is it this area [indicating]?
- A. Yeah. There's arrow indicating this area is
- 25 squamous mucosa.

- Q. Okay. So based on that evidence, the location
- 2 of the fiber --
- 3 A. Yeah.
- Q. -- to the identification of squamous mucosa --
- 5 A. Right. Because squamous mucosa, that's on the
- 6 top.
- 7 Q. So does that give you the ability to say to a
- 8 reasonable degree of medical probability or certainty
- 9 that's the area where the exposure occurred?
- 10 MR. VOUDOURIS: Objection.
- 11 A. I say the probable or possible area. It's not
- 12 like definitively -- there is no definitive evidence
- 13 saying, you know, from the specimen I examined shows the
- 14 mesh exposure or erosive site.
- Q. (BY MR. THORNBURGH) Okay. I mean, you
- 16 just -- you don't use the word "possible" in your -- in
- 17 your report. You actually say probable?
- 18 A. Right.
- 19 Q. Okay. So do you agree that that's the
- 20 probable location of the mesh exposure?
- A. Right. That's -- that's clearly in my report,
- 22 right?

- Q. So I'm going to write "exposure" here, okay?
- 24 On Page 14 of your report.
 - A. Should be probable exposure.

1

- 1 Q. Sure. Did you see -- do you see any
- ² evidence -- strike that.
- Okay. Figure 6 is -- I think that's your
- 4 last figure, right?
 - A. There's more than that.
- 6 Q. So Figure 6, briefly, you said this is --
- 7 shows good tissue integration, right?
- 8 A. Yes.

5

- 9 Q. And then you point to vessels that are -- how
- 10 many -- how -- what's the distance of those vessels
- 11 outside of the --
- A. It's less than a millimeter away.
- Q. Okay. So -- so you say this is good tissue
- 14 integration, and then you have arrows to the vessels.
- ¹⁵ And is the basis for your opinion the presence of the
- 16 vessels?
- A. Presence of vessels and also viable
- ¹⁸ fibroblasts and some nerve endings.
- Q. What's the degree of fibrosis over here --
- 20 A. It's still --
- 21 O. -- closest --
- A. Yeah.
- O. -- closest to the mesh fiber?
- A. So this still, overall, is mild in this area.
- ²⁵ And then -- except this area may be, if you want, is
 - Page 231

- 1 moderate.
- Q. Okay. Can you go ahead and draw an arrow to
- 3 that in the margin so we can see it?
- 4 A. Right in this -- overall, this large amount of
- 5 area there, all mild.
- 6 Q. What's your basis for stating that
- 7 this -- these areas that you circled are mild?
- 8 A. Because you have viable fibroblasts and also
- ⁹ vessels in it. And then you have, compared to other
- 10 tissue away from this area, without any fibrosis here,
- 11 you have more fibrous collagen.
- Q. Furthest -- further away from the mesh
- 13 filaments, right?
- 14 A. Right. Further away from mesh filaments,
- 15 there is no fibrosis.
- Q. And not in between -- the space between the
- 17 pores?
- A. Space between the pores, most of them, they
- ¹⁹ are still mild, but only very focal area, very close
- 20 area, you have some moderate degree, but it's --
- 21 Q. But that's --
- A. -- it's a tiny, tiny place.
- Q. You don't see vessels in between the mesh
- 24 pores? You've drawn arrows to -- for, but you haven't
- 25 drawn any arrows between the mesh pores, right?

- Page 232 MR. VOUDOURIS: Objection; compound.
- 2 A. And there is another one. If you want, this
- 3 is another one. Because there is no reason to indicate
- 4 every single vessels in it. Overall situation, if you
- 5 are trained pathologist, they're easily understand these
- 6 area they're healthy. They have innervation, as well as
- 7 a vascularization; therefore, they are viable tissue.
- Q. (BY MR. THORNBURGH) Is it your opinion that
- 9 the -- that the tissue over here where you've pointed to
- 10 the vessels, which is a lighter color stain --
- 11 A. Right.

12

15

24

- Q. -- is a better, more viable tissue than the
- 13 tissue that is closest to the mesh --
- 14 A. They're all viable so far.
 - Q. Which tissue looks healthier to you?
- MR. VOUDOURIS: Objection; form.
- 17 A. These are all healthy tissue look for me.
 - Q. (BY MR. THORNBURGH) So -- so are you stating
- 19 that this area right here next to where you -- where you
- 20 have the arrows to the vessels further away from the
- 21 fibers is the same type of reaction that you're seeing
- 22 closest to the fibers?
- MR. VOUDOURIS: Objection; form.
 - A. It's very much similar but just a less degree
- 25 of fibrosis.

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- Q. (BY MR. THORNBURGH) Greater degree of
- ² fibrosis closest to the fibers?
- 3 A. We already say that.
- 4 Q. That's a common finding?
- 5 A. Yeah; it's a very common finding.
- 6 Q. Figure 7, you say -- so this is your S-100
- 7 comparison to H&E?
- 8 A. Yes.
- 9 Q. And -- and what are you trying to demonstrate
- 10 in this -- in this exhibit, this figure on Page 16?
- 11 A. The overall demonstration point is amount of
- 12 nerve fibers identified in the specimen is within normal
- 13 limits.
- Q. And normal limits compared to what?
- A. I mean, it's a normal finding. Vaginal tissue
- should have no fibers.
- Q. So you're not surprised to find nerves near
- 18 mesh fiber?
- A. Not at all. If I don't find any, then
- 20 probably is a problem.
- Q. Is it -- let me try and understand quickly
- about your opinion regarding pain and the finding ofnerves.
- is herves.

- MR. VOUDOURIS: Dan...
 - Q. (BY MR. THORNBURGH) Is it -- is it your

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	Page 234		Page 236
	opinion in this case, in Mrs in Mrs. Corbet's case,	1	Q. (BY MR. THORNBURGH) I think so.
	2 that simply because there are nerves within a mesh	2	So you're saying, I think, that you can't
	specimen and nerves near the mesh fibers that strike	3	reliably look at a mesh specimen and see nerves present
	4 that.	4	in or around Ms. Corbet's mesh and conclude that it's
	You're not saying, I don't think, that the	5	the presence of the mesh is causing her pain?
	presence strike that. Let me ask a better question.	6	MR. VOUDOURIS: Objection; form.
	You're not offering an opinion that nerve	7	A. Nobody can
	damage in Mrs. Corbet's case didn't lead to her pain,	8	Q. (BY MR. THORNBURGH) Presence of the nerve
	9 right?	9	A. Yes. I can't, and I don't think any other
1	MR. VOUDOURIS: Objection to form.	10	pathologist can.
1	A. First of all, I never say that	11	Q. Is it possible for Mrs. Corbet that the
1	MR. VOUDOURIS: And you're misrepresenting	12	presence of nerves in and around her mesh contributed to
1	3 what he said.	13	her pain?
1	A. First of all, I never said said that there	14	MR. VOUDOURIS: Objection; form,
1	5 is any evidence of nerve damage, number one. Number two	15	foundation, and asked and answered.
1	5 is presence of nerve in these specimen is a normal	16	A. You're asking a hypothesis or assumption.
1	7 finding. Number three, from histological point of view,	17	I I don't know how to answer that question.
1	I can't say because presence of nerve in this specimen,	18	Q. (BY MR. THORNBURGH) Well, what are the for
1	9 that's correlated to patient pain. That's the three	19	Mrs. Corbet what are the potential causes of her pain,
2	points I want to say.	20	which led to the explant of the TVT device?
2	Q. (BY MR. THORNBURGH) Okay. So essentially, I	21	MR. VOUDOURIS: Objection; form,
2	think, if I could just boil it down, it's your opinion	22	foundation, beyond his scope.
2	3 that a pathologist can't opine that the clinical	23	THE WITNESS: That that means I don't
2	4 findings of vaginal pain are caused based on presence of	24	have to answer?
2	5 nerve fibers found within a mesh specimen slide; is that	25	MR. VOUDOURIS: Well, you've already
	Page 235		Page 237
	1 correct?	1	you've already testified that you can't look from a
	2 MR. VOUDOURIS: Objection; form.	2	pathologist's point of view
	A. I only can say based on the finding of this	3	THE WITNESS: Right.
	4 particular case, there is no evidence for me to say	4	MR. VOUDOURIS: at the slides and
	5 these nerves' presence in the specimen predicts the pain	5	correlate it with a complaint of pain.
	5 in the clinical site. Is that clear?	6	Q. (BY MR. THORNBURGH) So you can't, and won't
	Q. (BY MR. THORNBURGH) So you're not saying that	7	at trial, offer an opinion to a reasonable degree of
	8 the presence of nerves within or around the mesh doesn't	8	medical certainty what the cause of Ms. Corbet's pain
	cause pain.	9	is, correct?
1		10	MR. VOUDOURIS: Objection; form,
1	Q. (BY MR. THORNBURGH) It can cause pain, right?	11	foundation.
1	MR. VOUDOURIS: Objection; form,	12	A. I'm not in the position to explain where is
1	3 foundation.	13	the source for this patient of dyspareunia she
1	A. Let me explain to you in this way: Nerve	14	complained because based on pathological findings, I do
1	5 peripheral nerve growth is part of the tissue	15	not see any evidence to correlate to the pain. That's
1	integration. That happens almost to every patient who	16	the statement.
1	7 received vaginal mesh implants, okay?	17	Q. (BY MR. THORNBURGH) And I just want to make
1	So that means even without examining	18	sure I understand. You also didn't find any other
1	9 all majority of the implant, the mesh, then majority	19	pathological finding, like a tumor or something else,
2	of these patients who received mesh implants, they do	20	that could be causing her pain, correct?
2	not complain pain. You understand the linkage, right?	21	A. Yeah. If I see
2	2 So therefore, finding these pain these	22	MR. VOUDOURIS: He just he just asked
2	3 nerve in the specimen for Mrs. Corbet cannot predict or	23	you if you did or didn't.
2	4 correlate or can say associate with the clinical	24	A. I didn't. But if I see a neuroma, for
2	5 complaint of pain. Is that clear?	25	instance, then, that could be a reasonable finding to be
		1	

- 1 associated with the pain.
- 2 Q. (BY MR. THORNBURGH) Okay. And you said
- 3 neuroma?
- 4 A. Yeah.
- 5 Q. What's a neuroma?
- 6 A. It's a -- it's a tumor of the nerve.
- 7 Q. So you didn't find any sort of -- there was no
- 8 pathological findings like that --
- 9 A. No.
- 10 Q. -- that would explain her pain?
- 11 A. Correct.
- Q. The only finding you have and have
- 13 demonstrated in these figures that you've attached to
- 14 your report are mesh explant specimens that contained
- 15 mesh, right?
- 16 A. Yeah.
- O. Some with occasional -- with increased
- 18 inflammatory response around the mesh fibers compared to
- 19 the further adjacent tissues?
- 20 MR. VOUDOURIS: Objection.
- A. My conclusion is in my report, all right?
- 22 That's clearly --
- Q. (BY MR. THORNBURGH) But my question is: You
- 24 didn't find any other pathological findings that could
- 25 explain pain, but you did find the presence of mesh,

- Page 240
 - A. That's depending on what kind of condition

1 explanted, there was moderate fibrosis, right?

- 3 they -- these individual patients had.
- 4 Q. For all -- all three groups, there's no
- 5 significant difference, remember?
- A. I -- I know that. But for this particular
- 7 patient, we do not see -- mainly, it is a very focal
- 8 area with moderate amount of information. The majority
- 9 of them, they are mild; and many areas, no inflammation.
- Q. On Figure 8, you have an image. It looks like
- 11 the same image with different stains and different --
 - A. Magnification.
- Q. -- magnification --
- 14 A. Yes.

12

- Q. -- is that right?
- And you have a square representing where
- 17 you've magnified the image?
- 18 A. Correct.
- Q. Okay. And so in exhibit -- or in Figure 8a,
- 20 that's just the trichrome stain, right?
- 21 A. Correct.
- Q. You're not offering any opinions based on
- 23 that; you're just showing what a trichrome stain of this
- 24 slide looks like?
- A. No. I want to show because Dr. Iakovlev

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- 1 nerves near the mesh, you found inflammatory response,
- 2 and chronic foreign body reaction, correct?
- 3 A. Correct.
- 4 Q. It's not possible for you, as a pathologist,
- 5 to say that those findings are causing her
- 6 complications, including pain, right?
- 7 MR. VOUDOURIS: Objection; form,
- 8 foundation, asked and answered.
- 9 A. Correct. And also nobody -- no other
- 10 pathologist can predict that based on these histological
- 11 findings.
- Q. (BY MR. THORNBURGH) Didn't Hill and his
- 13 coauthors identify women who had pain and associated
- 14 increases of inflammation and chronic foreign body
- 15 reaction?
- MR. VOUDOURIS: Objection; form.
- A. I'm not sure for that particular point, but if
- 18 you have read in -- you know, you can just read.
- MR. VOUDOURIS: Audra Jolyn Hill might be
- 20 a little disappointed that you referred to her as a he.
- Q. (BY MR. THORNBURGH) Mrs. Hill --
- MR. VOUDOURIS: No. Dr. Hill.
- 23 MR. THORNBURGH: Dr. Hill.
- Q. (BY MR. THORNBURGH) Dr. Hill found that for
- 25 nearly 60 percent of the patients who had mesh

1 showed very lower power use trichrome stain, says

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- ² because all these blue color represent the fibrosis.
- 3 Therefore, he conclude these are the severe fibrosis or
- 4 scar everywhere. Then I try to show the same area from
- 5 the slides he took the picture then magnify gradually to
- 6 see these are not scar tissue. That's the point I want
- 7 to show.
- 8 Q. Okay. So Figure B is a -- what magnification,
- 9 on Page 22 of your report?
- 10 A. B are probably -- panel A is 40X, then panel B
- 11 is a 40X too.

- Q. And that's 40X in H&E, right?
- 13 A. Right.
- Q. Okay. And then you -- and what's the distance
- 15 from the fiber to that area, which looks like it's --
- A. It's within less than a millimeter. It's only
- 17 maybe half a millimeter away.
- Q. 500 microns or so?
- A. Yeah. You can see the mesh fiber is about
- 20 maybe 100 -- 100-micron cross-section diameters;
- therefore, you only have 2- to 300 microns.
 - Q. So it's not -- it wouldn't be immediately
- adjacent to the mesh; it would be further out?
- A. It's 2- to 300 micron. Basically, it's quite
- close already. It's a micron level.

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- 1 Q. And it's not in between the mesh pores, right?
- 2 A. It's -- it's not mesh pores.
- 3 Q. It's outside of the mesh pores, correct?
- A. It's -- could be still within the pore
- 5 because, as I said, two-dimensional pictures, you can't
- 6 tell within the pore or it's outside the pore or
- ⁷ adjacent to the pore. So basically, what we candidly
- 8 describe is adjacent to the mesh. You understand?
- 9 Q. Well, I don't understand how it could be
- 10 within a pore. Because if we look at your images,
- 11 right, look at --
- A. That's --12
- 13 Q. -- look at B --
- 14 A. Right.
- 15 Q. -- it -- it showed -- it appears to show that
- 16 it's -- it's not between these two pores if it's not on
- ¹⁷ the slide.
- 18 A. It's adjacent to the pore.
- 19 Q. It's adjacent, but not in between.
- 20 A. Doesn't matter. In between is theoretically
- 21 also adjacent; because in between, that is not necessary
- 22 it's within the pore.
- Q. Well, do you see any other pores on this side
- ²⁴ adjacent to the -- the microvessel that you've circled
- 25 there or squared there?

- A. Here is a -- is a space. So I don't know what 1
- 2 kind of space is that.
- 3 Q. Does it look like a pore?
- 4 MR. VOUDOURIS: Objection.
- 5 Q. (BY MR. THORNBURGH) It's too big to be a pore
- 6 in that space, right?
- 7 A. No.
- 8 MR. VOUDOURIS: Objection.
- 9 A. No. This is the tissue, missed portion of the
- 10 tissue there.
- 11 Q. (BY MR. THORNBURGH) You're not going
- 12 to -- you're not representing to the Court or to the
- 13 ladies and gentlemen of the jury, and won't at trial,
- 14 that this microvessel is in between the mesh pores,
- 15 right?
- 16 A. What -- you see the Figure A, panel A, is a
- 17 trichrome staining, right, it's a lower power trichrome
- 18 staining. In the center, that's mesh fiber spaces.
- 19 Then adjacent, they are all fibroconnective tissue,
- 20 right?
- Q. Yeah. I'm just -- I'm just going to 21
- 22 make -- I'm just making sure that at trial you're not
- 23 going to suggest or represent to the Court or opine or
- 24 offer an opinion that this microvessel is in between
- 25 pores, is filling the space of --

- A. I didn't say that. I said just -- the tissue
- 2 immediate adjacent to the mesh fibers, they represent
- 3 integrated tissue instead of pure scar. That's the
- Q. Does it appear that this is closest to the
- edge of the scar rather than the center of the --
 - A. This is not the scar.
- Q. -- fibroconnective tissue?
 - MR. VOUDOURIS: Objection; form.
- 10 Q. (BY MR. THORNBURGH) Let me ask it again.
- 11 Does it appear that this -- this area that you've
- identified as a microvessel is -- is closer to the edge
- of this fibroconnective tissue?
- A. It's not -- this specimen just like this area,
- 15 okay [indicating]? Okay, like panel A. And because
- different levels and you show these area, Dr. Iakovlev
- says they are all scar tissue.
- And my point is, these area, they not scar
- tissue. Because if you magnify a little bit, you can
- see viable vessel, as well as viable fibroblasts;
- therefore, they are not scar tissue. That's the point.
- 22 Q. Figure 9 -- when you say "scar tissue," you're
- 23 not -- are you saying they're not mature --
- 24 A. They're not pure scar.
- 25 MR. VOUDOURIS: Objection.

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- Q. (BY MR. THORNBURGH) Pure scar. And pure scar
- 2 would be?
- A. Pure scar will be just like Dr. Hill say, like
- this picture [indicating].
- Q. Okay. So how long -- do you know how
- 6 long -- how -- strike that.
- You don't know how long this mesh was
- implanted in this particular patient, right?
- 9 A. He -- she only presented as an example.
- 10 Q. And by "this particular patient," I'm talking
- 11 about this figure --
- 12 A. We don't know what kind of condition.
- Q. -- Figure E on Page 594 of Dr. Hill's article, 13
- 14 right?
- 15
- 16 Q. And how long was Mrs. Corbet's mesh implanted
- 17 in her?
- 18 A. It's about one year, right?
- 19 Q. July 2011 until early 2013?
- 20 MR. VOUDOURIS: February 2013.
- 21 A. It's over -- a little over a year.
- Q. (BY MR. THORNBURGH) Approximately a year and 22
- 23 a half?
- 24 A. Yeah.
- Q. Okay. And you know from -- you understand 25

Page 246 Page 248 1 that the tissue response is chronic and lasts for years? A. I think like this, the Figure 11, is higher 2 MR. VOUDOURIS: Objection; form. 2 magnification, which is at least 100 or 200. Okay? 3 A. Assuming the foreign body there, usually, yes, 3 Q. You could have gotten closer on that 4 you will -- will have more or less inflammatory magnification, right? 5 response. A. And because usually closer is not that good. Q. (BY MR. THORNBURGH) Do you know how long it 6 6 Because here, you can see clearly to see the takes to get a -- what you call a pure scar tissue? 7 illustration between the true mesh versus bark, all 8 MR. VOUDOURIS: Dan, this was covered right? Everybody can see very clearly. That's the ad infinitum in his prior depositions. point. If it's not very clear, then I will actually 9 10 MR. THORNBURGH: Okay. magnify to make it clear. 11 Q. (BY MR. THORNBURGH) Do you have any opinions 11 Q. If we look at, for example, Page 60 -- hold on 12 with respect to Mrs. Corbet, whether or not if the mesh a second -- 24 of Dr. Iakovlev's report. 13 had remained in her body for longer, that it would 13 A. Page 24? continue to experience increased inflammatory response 14 Q. Uh-huh. and foreign body reaction? MR. VOUDOURIS: What page? I'm sorry. 15 16 MR. VOUDOURIS: Objection; form, 16 MR. THORNBURGH: 24 of -- I'm sorry -- 65, 17 foundation --17 image 24b. 18 Q. (BY MR. THORNBURGH) It -- it would seem --18 MR. VOUDOURIS: Page --19 MR. VOUDOURIS: -- speculation. 19 MR. THORNBURGH: 24b. Q. (BY MR. THORNBURGH) The foreign body response 20 20 MR. SNOWDEN: Counsel, do you want to use and inflammatory response would be persistent and remain 21 the Corbet portion of deposition or no? 21 constant for the mesh that's still in her body? 22 22 MR. THORNBURGH: I was going to ask what 23 MR. VOUDOURIS: Objection; form. 23 the magnification is on -- on this image. A. I'm not able to predict the things is not 24 MR. SNOWDEN: Is that for Ms. Corbet? 25 happening yet, first of all. But in general, yes, if 25 MR. THORNBURGH: I'm comparing to the Page 249 Page 247 1 you have implanted the mesh, then inflammatory response 1 magnification that he used in his report. 2 or tissue response will continue. MR. VOUDOURIS: Yeah, so --Then the degree of -- of inflammation or 3 MR. THORNBURGH: I'm just -- I'm just 4 degree of fibrosis, that's individualized rather than 5 just you can draw an equation that says how many days Q. (BY MR. THORNBURGH) This magnification on 6 there then will reach to a certain level. No. Every 6 Page 65, in 24b is a higher magnification than what you patient is different. used in Figure 9, right? Q. (BY MR. THORNBURGH) Your -- your Figure 9, A. That's a lot higher. 8 8 9 the -- the images that you took, is a section that Q. Okay. And how much higher; do you know? 10 you're -- you've sort of dedicated to the degradation or 10 A. I don't know. Maybe still like either 11 your opinions concerning degradation? solvent, something -- oil lens. That's the tool he 11 12 A. Concerning his so-called bark-like area, 12 13 right? 13 Q. If you turn to Page 116 of Dr. Iakovlev's Q. Yes. On Page 24, you've got image A, B, and report, Figure CK8b, this is an image of Ms. Corbet, 15 C, and you took that in a low magnification, right? 15 right? 16 16 A. Yes. A. It's not really low. You can see. 17 17 Q. What's the magnification on exhibit A, B, Q. Okay. Do you -- that's a much higher 18 and C? 18 magnification than you used --19 19 A. Did I say that? Oh, no. A. Right. 20 20 Q. -- in your figures -- the figures contained A. Based on this one, most likely will be 40 or within Figure 9 and Figure 10, right? 21 21 22 100. 22 A. Right.

23

24 magnification to get closer to the edge of the mesh

Q. Did you take any additional images with higher

23

25 fibers?

Q. And if the bark or the surface layer

of -- surrounding the mesh fibers is 2 to 5 microns,

25 wouldn't you agree that to get a better image, you need

 $\label{eq:page 250} Page \ 250$ $1 \ \ to \ have a stronger-powered zoom?$

- 2 A. No.
- 3 MR. VOUDOURIS: Objection; form,
- 4 foundation.
- 5 A. I disagree because the point here is if these
- 6 bark-like material, they represent degraded mesh
- 7 material, then under the polarized condition, they will
- 8 show identical birefringing condition. That's the point
- 9 I want to show.
- And what he wants to show is a very high
- 11 magnification is to show these cracks-like stuff there,
- 12 all right? And which is usually -- I don't like to use
- 13 this kind of very high magnification.
- 14 If they do want to show, then he should
- 15 include a lower magnification, show the area he's
- 16 pointing. That will be much better picture than to
- 17 demonstrate some points, right? Even I don't know where
- 18 this coming from. If you show higher magnification
- 19 from -- for instance, if I show my finger is blown into
- 20 1,000 times, nobody can tell this from my finger.
- 21 Q. (BY MR. THORNBURGH) So you think it would be
- 22 better for him to start out --
- 23 A. Right. Start it from lower power, then
- 24 gradually --
- Q. Zoom in?

- 1 pathology practice.
 - Q. Did you use oil immersion?
 - 3 A. No. As I said, surgical pathologists, the
 - 4 highest magnification is 400. And the oil immersion is

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- 5 for microbiologist or cytopathologist.
- Q. So -- so you didn't use oil immersion because
- 7 you're only going to look at the specimen using 40
- 8 magnification?
- 9 MR. VOUDOURIS: Objection; form.
- 10 A. 400 -- highest is 400.
- Q. (BY MR. THORNBURGH) So -- so the reason why
- 12 you didn't use oil immersion is because you were only
- 13 going to go as high as -- you say 400, but are any of
- 14 these 400?
- 15 A. These are not hundred, but can be -- can go
- 16 to -- highest is 400. It's really not necessary to use
- 17 oil immersion lens.
- 18 Q. Unless you're going to do a higher
- 19 magnification?
- A. For me, there is no point to do that; no point
- 21 to go further high.
- Q. So, you know, on Figure CK8b on Page 116,
- 23 Dr. Iakovlev says that he -- this was a degraded layer
- 24 of bark, polypropylene, seen using H&E 100X subjective
- 25 with oil immersion polarized light.

- A. Right. Okay. So this point, I use the
- ² intermediate power is simply try to demonstrate one
- ³ is -- clear-cut is a mesh, remaining mesh, right, in
- 4 the -- in the center. You see the different color and
- the different -- one is blue, one is yellow, the otheris green.
- 7 Q. Uh-huh.
- 8 A. Why is that? Because in the polarized
- ⁹ condition, these mesh fibers show polarized or
- 10 birefringent property, right? And then --
- 11 O. Uh-huh.
- 12 A. -- the bark material he claim -- and whatever
- 13 he claim, that they -- all these bark represent degraded
- 14 mesh, they should have showed similar birefringent
- 15 property. But this picture shows opposite.
- Q. How many filters did you use, polarized
- 17 filters?
- 18 A. How many filters?
- 19 Q. Yeah.
- A. What do you mean? It's a typical, standard
- 21 birefringent -- polarized filter.
- Q. So it's one -- one polarized filter?
- A. Yes. One is on the top, the other is --
- Q. On the bottom?
- A. -- on the bottom. Right. It's a standard

- 1 A. Right. He --
- Q. This indicates he's using 100X, right?
- 3 A. 100X means to 1,000 magnification.
- 4 Q. Okay. And your magnification was as high as
- 5 what on these images in Figures 9 and 10?
- 6 A. That's why I -- that's how I say probably
- ⁷ is -- maximum is -- is 100.
- Q. So that would be 4X and 10X?
- 9 A. It's either 4X or 10X then become either 40 or
- 10 100.
- Q. Did you attempt to go to 1,000 magnification
- 12 or 100X?
- A. There is no reason to do that. That's why I
- 14 say -- if I magnify too high, then the remaining tissue,
- 15 you cannot see. Even if the -- then people can ask me,
- 16 "Where this coming from?"
- Q. Okay. So -- and that's why you didn't use oil
- 18 immersion because you don't --
- A. Right. That's why -- that's the same question
- 20 I'm going to ask you: "Where this coming from?" I
- 21 don't know.
- Q. Let me finish the question. You didn't -- you
- 23 didn't use oil immersion because you weren't going --
- 24 going to magnify up to 1,000?
- A. There is no reason --

Case 2:12-md-02327 Document 2834-4 Wenx Filed 09/19/16 Page 66 of 73 PageID #: 98343 in Zheng, M.B. Page 254 Page 256 1 MR. VOUDOURIS: Objection. 1 things he use or arrows indicate that. This could be --2 A. -- as I said. 2 well be like artifact we just discussed earlier in the 3 Q. (BY MR. THORNBURGH) Have you ever -- strike 3 morning through the blades. We don't know what's going 4 that. 4 on for this one. So there -- this picture did not 5 Did you place the polarized -- hold on a demonstrate anything at all for me. second. Strike that. Q. (BY MR. THORNBURGH) Are you claiming that 6 Dr. Iakovlev, on -- on Page 116, says, "If those cracks that we see on the outer surface of this 8 there is an object with polarizing properties between fiber is artifact? 9 the filters, the light plane deviates from the A. We don't know what -- I did not claim. As I 10 perpendicular plane, and the object becomes visible" [as said, there is a possibility because nobody can confirm 11 read]. what are those stuff. 12 12 Q. Okay. Do you see that? 13 A. Which line is that? 13 A. Because you magnify to the 1,000 times and 14 Q. So let's -- let's go a couple lines. So if then to see a very tiny area showing these so-called you go to "When two polarizing filters were placed above irregularity, or these lines, on the surface of the and below the glass slide" [as read]. polymer fiber. 17 Do you see that last sentence? Q. You keep on saying we don't know where this 18 A. Okay. The second line, yes. image is coming from, but he's identified that in -- on 19 Q. -- "and their polarizing orientation is Page 116. You see that, right? The same fields are in 20 perpendicular, their light cannot pass through. 20 CK5a. 21 However, if there is an object with polarizing 21 A. I know. I would say that where this coming 22 properties between the filters, the light plane deviates from, CK5a is of which -- corresponding to which picture from the perpendicular plane, and the object becomes of the -- of the H&E slide. visible" [as read]. 24 Q. So are -- let me just make sure I understand. 25 Are your criticisms that, number one, you don't know Do you have any basis to disagree with Page 255 Page 257 1 that statement? 1 where this fiber is coming from, this fiber image? A. This is fine because these are the polarized, 2 A. Right. 3 the -- the nature of the polarized lens, when you use 3 Q. Number two, he used 100X objective --4 that, and you can see these things. Q. -- to get close up on the image? Q. Did you use that same method when you did the polarization --A. That's very high. That's 1,000 times A. Yes. magnification. 8 Q. -- in Figure 9 and 10? 8 Q. And what are your other criticisms of this 9 A. That's routine practice for pathology. 9 10 Q. Why -- why is -- why are his images darker 10 A. And then his -- his arrows indicating -- let's 11 than your images? 11 read -- what's the -- arrow indicating what? 12 MR. VOUDOURIS: Objection. 12 (Witness reviewed document.) 13 Q. (BY MR. THORNBURGH) Is there a way to add Q. Blue -- blue granules. Do you -- do you know additional -- to keep -- to continue to polarize that the -- do you have an understanding that this TVT 15 the -- the filters to get a different image like he's mesh is made from a blue pigment? got on figure CK8b? 16 A. Yes. 16 17

17 MR. VOUDOURIS: Objection.

18 A. Polarize the condition. If you turn the

polarized lens a little bit, like 5 degree, then you see

different picture, different color, okay? Then why this

is black -- and first of all, I don't know where this

coming from, number one. All right?

23 Number two, he say that there is H&E

24 associated. Where is the H&E?

25 Number 3, all these so-called cracks-like Q. And so do you understand that what he's

pointing out here are -- are that there are blue

pigments that the polypropylene is made from within the

20 cracked layer?

21 MR. VOUDOURIS: Objection.

22 A. And, again, he cannot prove there is something

overlapping. For instance, you have collagens densely

adhesed to these mesh fibers also can show overlapping.

Underneath is mesh fiber on H and you -- meanwhile, you

se 2	:12-md-02327 Document 2834-4 Filed 09 Wenxin Zh	<mark>9/1</mark>	9/16 Page 67 of 73 PageID #: 98344
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1	have dense collagens adhesed to that. Then these	1	A. Meanwhile, it's a purplish.
2	collagen also can show linings or cracks, so-called.	2	Q. (BY MR. THORNBURGH) You see those purplish
3	Q. (BY MR. THORNBURGH) Okay. So you understand	3	A. Right.
4	this is a cross-section, right?	4	Q dots or pigments within the or granules
5	A. Yes.	5	within the cracked layer?
6	Q. So you're claiming that this this outer,	6	A. The purplish is staining, right. And
7	cracked layer is collagen, right? Is that what you're	7	underneath, you may have a few granules. That's a
8	claiming?	8	possibility.
9	A. I said could be collagen overlapping in this	9	Q. Within the cracked layer?
10	area.	10	A. Right.
11	Q. Okay. But what he's pointing out here is	11	Q. And if there are granules within the cracked
12		12	
13	fibers are dyed with, and he observes them within the	13	
14	cracked area.	14	
15	A. Correct.		into Mrs. Corbet?
16	MR. VOUDOURIS: Objection; form.	16	MR. VOUDOURIS: Objection; form,
17	A. That's why I I say they could be		foundation, speculation.
18	overlapping. And under microscope, in certain	18	A. You can't confirm that. Okay. Again, just
19	condition, you can still see blue granules. Meanwhile,		like as I said, there is a possibility you have these
20	the the collagen covers on the top. You are not able	20	overlapping so-called degenerated collagens densely
21		21	adhesed to the mesh fiber or mesh filament. Then
22	Q. (BY MR. THORNBURGH) Do you have any evidence		underneath of that, you see blue granule is very common.
		22	
23		23	
24	A. It's my understanding; it's not evidence	24	Q. (BY MR. THORNBURGH) So it's very so I
25	based. It's my based on my past experience as a	25	think what I understood you to say is it's very common
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1	pathologist. Because, think it over, the mesh will stay	1	for you to when you look at these explanted meshes on
2	in the human body. It's not going to move around	2	cross-section at a higher magnification to see these
3	because you have tissue integration. Why tissue	3	blue granules within the layer, the top layer of the
4	integration will hold mesh? Because you have these	4	mesh
5	collagens densely adhesed to the mesh fiber, anchors and	5	MR. VOUDOURIS: Objection; form.
6	fix these mesh fibers.	6	Q. (BY MR. THORNBURGH) filament?
7	Q. Go to Page 119 real quick, Exhibit CK8f.	7	A. No. It's
8	A. Yes.	8	MR. VOUDOURIS: Misstates his testimony.
9	Q. And do you see that cracked, outer layer	9	A. In the 40X or 400 magnification, usually
10		10	
11	fiber?	11	plus, it's really not necessary to magnify such a high
12			level to visualize what are they because the best way to
13	A. Yes, I saw that.		show is if they are truly degraded mesh fibers, then
14			
	is a cross-section of Mrs. Corbet's explant, right?	15	
16	2		fact.
		17	
17		١	Q. (BY MR. THORNBURGH) If you turn the page to
	right?	18	26. Again, this is a lower magnification than
19	A. Yes.	19	Dr. Iakovlev uses, right?
20	Q. Have you ever looked at any mesh fibers in	20	A. This is a 400 probably.
	this case, Ms. Corbet's case, at 100X objective?	21	Q. 400X?
22	A. No. I there is no need to do that.	22	A. Yeah. Magnification, I mean.

23

24

25

24 within the cracked layer?

Q. Okay. And you see again those blue pigments

MR. VOUDOURIS: Objection; form.

23

25

Q. 400 magnification, which would be 40X, right?

Q. And you write here that "The bark-like

A. 40X is a 400 magnification.

- 1 material does not show the same birefringent properties
- 2 under the polarized light as the mesh fibers in your
- 3 image using 40X"?
- 4 A. Correct.
- 5 Q. Do you know how thick that layer is that
- 6 you're pointing to?
 - A. It's several microns, like still similar to
- 8 maybe 3 to 5 micron, as Dr. Iakovlev mentioned.
- 9 Q. And is this something that -- well, strike
- 10 that.
- Did you see this layer in Mrs. -- in all
- 12 of Ms. Corbet's fibers or just the ones that you used to
- 13 do polarized light?
- MR. VOUDOURIS: Objection; compound.
- 15 A. Can you rephrase your question?
- Q. (BY MR. THORNBURGH) Yeah. I'm just trying to
- 17 understand, did you -- when you looked at all of her
- 18 images --
- 19 A. Right.
- Q. -- did you try and get close enough to see if
- 21 there was an outer layer on the outside of the
- 22 cross-section fiber?
- A. Yes. I examined it very carefully.
- Q. And were you able to see an outer layer on the
- 25 mesh fibers at 40X?

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- 1 show similar pictures? What do you mean by that?
- A. Because mesh, just like Dr. Iakovlev's picture
- 3 and my picture, you can see lower power they can have
- 4 this kind of appearance or may have different
- 5 appearance, right? These -- depending on the -- which
- 6 plane you cut.
- 7 So it does not necessarily -- they are not
- 8 perfectly round, and then -- then these mesh, they are
- 9 normal. And then the relationship, like this mesh is
- 10 round, the other mesh is oval shape. Then they are
- 11 perpendicular relationship, then it says it's distorted.
- 12 Q. Did you see --
- 13 A. Nobody can say that.
- Q. Did you see in Dr. Iakovlev's report where he
- discusses where he can see evidence of curling and
- 16 roping?
- 17 A. Yeah. I -- I saw that, but I disagree.
- Q. And what -- and what's your basis for
- 19 disagreeing?
- 20 MR. VOUDOURIS: Objection; asked and
- 21 answered.
- 22 A. Can you show exactly which picture that you
- 23 are referring? Then we will discuss.
- Q. (BY MR. THORNBURGH) Yeah. Let me just -- you
- 25 know the -- the image that you have where you have --

- 1 MR. VOUDOURIS: Objection; form.
- A. Oh, yeah; it's very clear. And the many
- 3 so-called bark-like area can be visualized even in the
- 4 40X magnification or 100X magnification.
- 5 Q. (BY MR. THORNBURGH) Okay. So on -- under
- 6 section D, your conclusions, you say, "Based on my
- 7 review of Ms. Corbet's pathology specimens, I conclude
- 8 the following: No evidence of mesh distortion is
- 9 identified" [as read]?
- 10 A. Correct.
- Q. And by "mesh distortion," are you referring to
- 12 curling or roping?
- A. Yeah. Curling, roping, and also including the
- 14 clinical examination, as stated by Dr. Smith. When she
- 15 removed the portion of the implants, she did not
- 16 describe any abnormality there.
- Q. And any other basis for that? Just a review
- 18 of the -- the -- the --
- 19 A. And --
- Q. -- pathology material?
- 21 A. Right. And histologically, all these mesh
- 22 pictures or figures I have seen, it's very common. Just
- 23 almost every explanted mesh will show, more or less,
- 24 similar pictures.
- Q. What -- what do you mean by more or less will

- 1 you identified the possible erosion?
- 2 A. Right.
- Q. And that was image -- you circled it on --
 - A. That's on Page 14.
- 5 Q. On Page 14?
- 6 A. Figure 5.
- Q. Page 14, Figure 5 is the slide that you --
- 8 microphotograph that you indicated earlier was a
- 9 probable exposure, right?
- 10 A. Correct.
- Q. And do you see any evidence that this is
- 12 laying flat, this -- this mesh that was explanted is
- 13 laying flat, or does it appear to be curled up here
- 14 where you see the squamous mucosa?
- MR. VOUDOURIS: Objection; form.
- A. If you understand the pathology a little
- better, then you may not ask this question because the
- 18 specimen process is a random cut, all right?
- And also, fresh specimen is different from
- 20 fixed specimen. Fresh specimen removed by surgeon and
- 21 have to be placed in the formalin. Then after in the
- formalin, then tissue being fixed. And by removing the
- 23 water components, therefore, the specimen shrinks, okay?
- So then after specimen shrinks, then these
- 25 pictures, these mesh can be either way, can be arranged

- 1 very randomly, all right? Even make not only this
- 2 circle, even can be completely go to this area
- 3 [indicating].
- 4 Q. (BY MR. THORNBURGH) Okay.
- 5 A. It does not mean this mesh just distorted.
- 6 Q. So let me just make sure I understand your
- 7 testimony. Do you -- you, I think, are agreeing that
- 8 the image on Page 14 of your report appears to be
- 9 distorted, but you cannot say that that was -- happened
- 10 inside her body rather than something that happened --
- 11 A. I--
- 12 Q. -- after --
- 13 A. -- I did --
- MR. VOUDOURIS: Are you done?
- MR. THORNBURGH: Yeah.
- MR. VOUDOURIS: Objection --
- 17 THE WITNESS: Okay.
- MR. VOUDOURIS: -- form and misstates his
- 19 prior testimony.
- 20 A. Right. I even didn't say this appeared to
- 21 curl. That's you -- what you are saying.
- Q. (BY MR. THORNBURGH) You said it could have
- 23 this image and --
- 24 A. Right. All these --
- Q. -- and you directed --
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- 1 A. What I said is all these findings, they are
- 2 normal finding, okay? Whatever the -- the mesh, they
- 3 can have a totally different picture, all right? Can
- 4 have more than 100 kind of different appearance under
- 5 microscope because the section can be totally different.
- 6 Q. Okay. So when I asked you -- when I said
- 7 distorted or when I was -- strike that.
- 8 When I was asking questions about
- 9 distortion, you said, referring to Exhibit Number 14,
- 10 that it could appear like this, and you created sort of
- 11 a roundish -- a round circle as you were demonstrating.
- 12 A. Right.
- Q. Do you see some evidence of -- of some sort of
- 14 curling that is happening within this image?
- 15 A. We --
- 16 MR. VOUDOURIS: Objection.
- 17 A. We see all kinds of microscopic
- 18 representations, including so-called curling. It's not
- 19 real curling, okay? Because, as I say, tissue, after
- 20 remove the water, tissue contracts. Then tissue
- 21 contracts, will change the shape of original mesh
- 22 in vivo. So it's totally different from in vivo.
- Q. (BY MR. THORNBURGH) Okay. So I think you're
- 24 saying that you can't tell whether or not in
- 25 Mrs. Corbet's case if there was any evidence of

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 distortion because the mesh was explanted and put into
- 2 formalin; is that right?
- 3 MR. VOUDOURIS: Objection; form.
- 4 A. That's why I say no -- no histological
- ⁵ evidence of distortion.
- Q. (BY MR. THORNBURGH) All right. So you're
- 7 not saying that -- you're not going to opine or offer
- 8 evidence or suggest that it didn't distort inside her
- body; you're just stating or offering an opinion that
- 10 you simply can't make that determination after the mesh
- 11 has been explanted and put into formalin?
- MR. VOUDOURIS: Objection; form,
- 13 foundation, misstates his testimony.
- 14 Go ahead.

15

- A. But based on clinical finding, Dr. Smith did
- 16 not state any abnormality, for instance, the -- the --
- 17 the implanted mesh was displaced or abnormally located,
- 18 okay? Number one.
- Number two, from other publications
- 20 also -- like ultrasound study also mention based on a
- 21 several-year follow-up -- I don't remember exactly where
- 22 it is -- they found that there is no evidence of -- you
- 23 know, that these implanted mesh will move around or
- 24 change shape.
- 25 Q. (BY MR. THORNBURGH) What study did you

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- 1 reference?
 - A. That's, I think, one of the study that's in
 - 3 the --
 - 4 Q. Is that the Klinge study?
- 5 A. I don't remember which one, but anyway, it's
- 6 in the thumb drive.
- 7 Q. Is that the study? And I'm not -- I
- 8 don't want to -- I'm just trying to understand what
- 9 study you're using to base your opinion --
- 0 A. It's an ultrasound study to see if mesh
- 11 actually move -- moved from the year 1 -- or day 1
- 12 implantation and then to after 3 years follow-up to
- 13 see --

- 14 Q. That's --
- 15 A. -- if they move at all.
- Q. That's actually the study where they began to
- 17 evaluate mesh movement after three months, right?
- MR. VOUDOURIS: Objection; form.
 - A. I think three years, three-year follow-up.
- Q. (BY MR. THORNBURGH) So that's your basis for
- 21 the opinion --
- A. It's not the basis. My basis is, first of
- all, based on my pathological finding, number one.
- They're very common, all right? Number two is from
- 25 Dr. Smith's deposition or surgical pathology report --

- 1 or surgical procedure report.
- Q. On number 2 you say the -- the second opinion
- ³ you have is that, "The specimen shows goods tissue
- 4 integration with mild and focally moderate degree of
- ⁵ fibrosis. No evidence of diffuse scar formation or scar
- 6 bridging is identified" [as read].
- 7 And is that the opinion that you have
- 8 given throughout today?
- 9 A. Yes.
- Q. "And no evidence of infection present," right?
- 11 A. Correct.
- Q. You say, "But focal mesh exposure or erosion
- 13 may be present" [as read].
- And that's what you identified?
- 15 A. That's what we discussed.
- Q. Your next opinion is, "No evidence of nerve
- 17 entrapment or any abnormal nerve findings in the
- 18 specimen" [as read]?
- 19 A. Correct.
- Q. And we discussed that earlier. And the basis
- 21 for that is your review of these -- is your
- 22 opinion -- or the basis for that opinion is that finding
- 23 nerves in -- in or near mesh is a normal finding?
- A. Correct.
- Q. "The degree of chronic inflammation of foreign

- 1 A. If -- if they are normal.
- Q. Normal limits -- when you say "normal limits,"

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- 3 you're comparing --
- 4 A. That means without infection, all these
- 5 things. If you -- if the specimen is infected, that's
- 6 different.
- 7 Q. You say here, "No evidence of tissue
- 8 necrosis," right?
- 9 A. Correct.
- Q. And -- and then go on to say that "Therefore,
- 11 there's no cytotoxicity"?
- 12 A. Correct.
- Q. Okay. And she did have -- as we've already
- 14 said, you've observed a probable exposure, and
- 15 clinically, she had an exposure. Are you offering an
- 16 opinion or stating, representing that when there's
- 17 cytotoxicity, it does not lead to erosions?
- MR. VOUDOURIS: Objection and compound.
- 19 A. I said there is no evidence here based on
- 20 histological findings to suggest any cytotoxicity
- 21 happened. Because if there is any evidence of
- 22 cytotoxicity, then we should be able to see cell deaths.
- Q. (BY MR. THORNBURGH) So, you know, I've taken
- 24 the deposition of, you know, internal employees for --
- for Ethicon, who've testified that cyto -- that the type

- 1 body giant cells found in the specimen is within normal
- 2 limits" [as read]?
- 3 A. Yes.
- 4 Q. And the norm -- you say "normal limits." For
- 5 what? What is normal limits?
- 6 A. Normal limits means almost every explanted
- 7 mesh should have, more or less, similar degree of
- 8 inflammation or fibrosis.
- 9 Q. So when you --
- 10 A. So that means it's -- it's not beyond
- 11 expectation.
- Q. So -- so what -- the way you used the term
- 13 "normal limits," you're saying that Mrs. Corbet's degree
- 14 of chronic inflammation of foreign giant cells found in
- 15 her specimen is consistent with the other specimens that
- 16 you've explanted or analyzed?
- A. Right. Or consistent with similar even
- 18 nonmesh implants or foreign body. Any foreign body
- 19 implant to human tissues, they normally -- in normal
- 20 condition, they should have similar findings.
- Q. Okay. So her findings -- the findings that
- 22 you have analyzing her explant is consistent with the
- 23 findings that you see in all foreign body explants?
- 24 A. Correct.
- Q. So normal --

- 1 of symptoms you would expect from cytotoxicity would be
- 2 an enhanced tissue response or erosion.
- 3 MR. VOUDOURIS: Objection.
- 4 Q. (BY MR. THORNBURGH) So are -- are you saying
- 5 that she -- that erosion is not a finding caused by
- 6 cytotoxicity?
- A. There is no relationship for that.
- Q. What's the basis for your opinion that
- 9 Mrs. Corbet's erosion does not suggest or indicate
- 10 cytotoxicity?
- 11 MR. VOUDOURIS: Objection; asked and
- 12 answered.
- 13 A. I have said very clearly here there is no
- 14 evidence of tissue necrosis or cell deaths in here;
- 15 therefore, unlikely there is any cytotoxicity there in
- 16 this -- these tissue from the mesh specimen.
- Q. (BY MR. THORNBURGH) You're not a
- 18 toxicologist, though, right?
- 19 A. No.
- 20 Q. You're not going to offer opinions as a
- 21 toxicologist at trial?
- 22 A. No.
- Q. Have you looked at, in making this opinion
 - about Mrs. Corbet, the internal documents of Ethicon
- concerning their cytotoxicity results?

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	Page 274		Page 276
1	A. No.	1	presence of inflammation is causing her pain?
2	Q. Have you read the deposition of Dr	2	A. Not only me; majority of the pathologists will
3	Dr. Barbolt concerning cytotoxicity?	3	have the same conclusion.
4	A. No.	4	Q. And so I think similar to your opinions that
5	Q. And so what's the basis where do you get	5	you offered regarding the nerves, are you basically
6	the this statement or the opinion that if it's	6	are you essentially saying that it's impossible to
7	cytotoxic, you're going to see necrosis?	7	determine that a patient's pain is caused from a
8	A. If it's cytotoxic, that means that these	8	pathological finding of inflammation?
9	chemicals will kill the cell. That's very simple. And	9	MR. VOUDOURIS: Objection.
10	I don't see cell deaths and even tissue necrosis.	10	A. Right. Pain is a clinical symptom and a
11	Therefore, from that point of view, there is no toxic	11	patient feeling. It's a very complex situation, okay?
12	environment there. Is that clear?	12	You understand? So that's
13	Q. Yeah. I'm just trying do you have an	13	Q. (BY MR. THORNBURGH) Inflammation I'm
14	opinion whether or not cytotoxicity can cause erosion?	14	
15	MR. VOUDOURIS: Objection; it's beyond the	15	Inflammation can cause pain, though,
16	scope.	16	right?
17	Q. (BY MR. THORNBURGH) You're not offering that	17	MR. VOUDOURIS: Objection.
18	opinion?	18	A. Depending on how much inflammation you have.
19	A. I'm not going to offer any opinion of that.	19	Q. (BY MR. THORNBURGH) Do you know sorry. Go
20	Q. Would you defer to people at Ethicon?	20	ahead.
21	A. Or the expert.	21	A. For instance, if you have a cut and infected,
22	Q. And finding there's no histological evidence	22	then lots of inflammation cause erythema, edema, and
23	to support pain or dyspareunia complained of in the	23	then you have you may have pain. But if you have a
24	patient, right?	24	mild, chronic inflammation many people have, then
25	A. From yes, from histological perspective,	25	we particularly, in majority situation, they do not
	Page 275		Page 277
1	Page 275 there is no evidence to support that.	1	
1 2	_	1 2	_
	there is no evidence to support that.		feel pain.
2 3	there is no evidence to support that. Q. So it's your opinion that the moderate	2	feel pain. MR. VOUDOURIS: Dan, this was
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	Page 278		Page 280
1	Could be loose connective tissue. So therefore, there's	1	CHANGES AND SIGNATURE
2	no evidence to support patient a clinical finding of	2	WITNESS NAME: WENXIN ZHENG, M.D. DATE: NOVEMBER 18, 2015
3	pain.	3	PAGE LINE CHANGE REASON
4	Q. (BY MR. THORNBURGH) Does that summarize all	4	
5	of your opinions?	5	
6	A. Correct.	6	
7	Q. And finally, I think you testified that you	7	
8	got paid \$600 an hour, but does that change for trial?	ر ا	
9	Do you get paid more for trial?	9	
		-	
10	A. No. I think this the same, always the same.		
11	Q. Okay. \$600 per hour? Is there a minimum		
12	hourly fee per day?		
13	A. For trial, I think I mentioned that the		
14	maximum will be either 8 hours or 10 hours, no	14	
15	matter I'm not going to include my sleeping hours	15	
16	for for the trial.	16	
17	Q. So so you'd get a minimum of \$8 per	17	
18	day I'm sorry a minimum of 8 hours per day at \$600	18	
19	an hour if you appear for trial?	19	
20	A. Usually that's the case.	20	
21	Q. Is that in a fee schedule?	21	
22	A. That's my fee schedule for many years, yes.	22	
23	MR. THORNBURGH: I think that's it.		
24	THE WITNESS: Okay.		
25	MR. VOUDOURIS: Let's just take a quick		
45	MR. VOODOORIS: Let's just take a quick	∠5	
	Page 279		Page 281
1	Page 279 break.	1	Page 281 I, WENXIN ZHENG, M.D., have read the foregoing
1 2	_	1	
	break. THE VIDEOGRAPHER: We're off record at		I, WENXIN ZHENG, M.D., have read the foregoing
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	Page 282	
	STATE OF TEXAS)	
	COUNTY OF DALLAS)	
3	I, LISA C. HUNDT, a Certified Shorthand Reporter in	
4	and for the State of Texas, hereby certify that,	
5	pursuant to the agreement hereinbefore set forth, there	
6	came before me on the 18th day of November, A.D, 2015,	
7	at 9:16 a.m., at the office of Thompson & Knight,	
8	located at 1722 Routh Street, Suite 1500, in the City of	
9	Dallas, State of Texas, the following named person,	
	to-wit: WENXIN ZHENG, M.D., who was by me duly	
11	cautioned and sworn to testify to the truth, the whole	
12	truth, and nothing but the truth of his knowledge	
13	8	
14	· · · · · · · · · · · · · · · · · · ·	
15	upon his oath and his examination reduced to writing	
16	under my supervision; that the deposition is a true	
17	record of the testimony given by the witness, same to be	
18	sworn and subscribed by said witness before any Notary	
19	Public, pursuant to the agreement of the parties; and	
20	that the amount of time used by each party at the	
21	deposition is as follows:	
22	Mr. Daniel Thornburgh - 6 hours, 22 minutes,	
23	Mr. Peter Voudouris - 0 hours, 0 minutes,	
24	Mr. Brandon Morris - 0 hours, 0 minutes,	
25	Mr. Andrew Snowden - 0 hours, 0 minutes;	
	Page 283	
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